

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES

APPROPRIATIONS FOR 2020

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTEENTH CONGRESS

FIRST SESSION

SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES,
EDUCATION, AND RELATED AGENCIES

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**DEPARTMENTS OF LABOR, HEALTH AND
HUMAN SERVICES, EDUCATION, AND RE-
LATED AGENCIES APPROPRIATIONS FOR
2020**

WEDNESDAY, JULY 24, 2019.

**OVERSIGHT OF THE UNACCOMPANIED CHILDREN PRO-
GRAM: ENSURING THE SAFETY OF CHILDREN IN HHS
CARE**

WITNESSES

**HON. DEBBIE WASSERMAN SCHULTZ, A REPRESENTATIVE IN CON-
GRESS FROM THE STATE OF FLORIDA**

**HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM
THE STATE OF TEXAS**

**HON. CLAY HIGGINS, A REPRESENTATIVE IN CONGRESS FROM THE
STATE OF LOUISIANA**

**HON. DONNA E. SHALALA, A REPRESENTATIVE IN CONGRESS FROM
THE STATE OF FLORIDA**

**LYNN JOHNSON, ASSISTANT SECRETARY, ADMINISTRATION FOR
CHILDREN AND FAMILIES**

**JONATHAN HAYES, DIRECTOR, OFFICE OF REFUGEE RESETTLEMENT
MARGARET HUANG, EXECUTIVE DIRECTOR, AMNESTY INTER-
NATIONAL USA**

**KRISH O'MARA VIGNARAJAH, PRESIDENT AND CEO, LUTHERAN IMMI-
GRATION AND REFUGEE SERVICE**

Ms. DELAURO. Good morning. Welcome everyone to the Labor, HHS, and Education Appropriations Subcommittee.

Today's oversight hearing will focus on the Office of Refugee Resettlement's Unaccompanied Children Program and its reliance on influx facilities that do not adhere to State or Federal standards of care for children. We have multiple panels today, and I want to thank each of our witnesses for being here.

We are starting this morning with testimony from several of our congressional colleagues. After hearing from our colleagues, we will proceed to a panel of senior officials from the Department of Health and Human Services who are responsible for administering the Unaccompanied Children Program. And finally, we will proceed to a panel of civil society experts with direct experience in child welfare and refugee services.

I will hold my opening remarks until the next panel, and my colleague Congressman Cole will hold his remarks, opening remarks for the second panel.

First, I would like to introduce Congresswoman Debbie Wasserman Schultz of Florida, a member of the Appropriations

Committee and chair of the Military Construction and Veterans Affairs Appropriations Subcommittee. I would also like to introduce Congressman Michael Burgess of Texas, a member of the Energy and Commerce Committee, as well as the Rules Committee.

Congresswoman Wasserman Schultz, your full testimony will be entered into the record. You are recognized for 5 minutes, and then, Congressman Burgess, again your testimony will be in the record, and you will be recognized for 5 minutes.

Congresswoman Wasserman Schultz.

Ms. WASSERMAN SCHULTZ. Thank you, Madam Chair. And I want to thank both you and the ranking member for giving up an opportunity this morning to share a little bit about our experiences, in my case, for the opportunity to testify today about my experience at the Homestead detention center in Homestead, Florida.

I appreciated the opportunity to accompany members of this subcommittee during a trip to the facility last week in my South Florida backyard. I visited or attempted to visit this facility four times now. I have only been allowed in twice.

I know the chairwoman submitted a request to the Office of Refugee Resettlement a week in advance of our visit most recently. This was all the time ORR needed to present a prefabricated tour that painted the rosiest picture possible. The red carpet was clearly rolled out for us. We were accompanied by the Director of ORR, who is testifying today, and the Deputy Assistant Secretary of HHS for Financial Resources.

The private contractor who operates this facility ushered us from one orchestrated stop to the next. It was tightly regimented. Our interactions with the detained children were limited. An employee always stood very close by. We were given greater access to four student council leaders who were chosen by the contractor.

A posted bulletin board had timelines dealing when staff would notify ICE about kids approaching their 18th birthday. These children had to be transferred out of Homestead and ORR care, and we were told these young adults are arrested by ICE, handcuffed, and sent to an ICE adult prison. Children often dread this date. Many become suicidal as the date nears.

I came away with far more questions than answers, and I believe many of you feel the same way. The most common answer to our specific questions was, "We will get back to you." I will briefly mention a few of my biggest concerns.

We learned extremely troubling information about the education program there. The private company running the facility performs an academic assessment, one the company made up themselves. We have no idea what standards they use, and children are not taught by certified teachers or, frequently, even by people with any teaching experience.

A second concern involves ORR's hurricane preparedness plan. We pressed the agency to share its plan to safeguard these children during a hurricane. ORR offered a briefing but refused to share any written details.

We are in the middle of hurricane season in Florida, and many of the structures there at the Homestead facility are tents. In order to ensure the safety of these children, there must be detailed and transparent evacuation and relocation plans. Comprehensive

Health Services will not even share the plan with the Florida Division of Emergency Management.

Finally, while it was good to learn that ORR has recently transitioned more than 1,000 children out of Homestead, they achieved this massive downsize in just 2 weeks. I have been calling for ORR to process children more quickly out of this prison-like facility since the last Congress. This rapid downsizing raises concerning questions. Why now? Why has ORR not expeditiously processed these children long before now?

In January, HHS announced that it was expanding Homestead from 1,350 beds to 2,350 beds after it claimed that ORR's capacity was being overloaded. Then HHS expanded the facility again in April, from 2,350 to 3,200. How can the agency reduce its numbers so quickly now, and where do these children go? How did ORR achieve this with such a limited case management capacity? I have heard from advocate groups back home that children have likely been shuffled to nonsecure ORR facilities and not to sponsor households, but this remains unclear.

Additionally, I have been frustrated by ORR and DHS's unwillingness to provide information on removal actions toward sponsors and potential sponsors. I worked with our colleagues on the Appropriations Committee to include language in the fiscal year 2019 appropriations package that prohibits DHS from initiating deportation proceedings against sponsors, potential sponsors, or a member of a sponsor household based on information shared by HHS.

This language was included to expedite the processing of unaccompanied minors out of this prison-like facility and into nurturing foster households. It is unclear if the administration has complied with this language because it has not provided information on the deportation of sponsors.

You can probably sense a theme running through my concerns, an absolute lack of transparency. It is my hope that this subcommittee will get solid, substantive answers from HHS and ORR today. I commit to keep working with you to hold this administration accountable. That is why I introduced the Homestead Act of 2019 this past Monday.

The bill would allow Members of Congress to visit HHS or DHS detention facilities without any prior notice. Congress must assert its duty to conduct oversight of this administration and ensure that children are treated with dignity and humanity. ORR recently announced that it will suspend sending children to Homestead, but we need to shut down this temporary prison-like facility, one that is unlicensed by the State of Florida and does not abide by State child welfare standards.

When I looked into the eyes of these children, I could not help but see my own children looking back at me. I shudder at the idea of my child or anyone's child living the way these poor children do. We just cannot turn our back on them.

Thank you again for the opportunity to testify today.

[The information follows:]

116TH CONGRESS
1ST SESSION

H. R. 3868

To grant Members of Congress access to detention facilities, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 22, 2019

Ms. WASSERMAN SCHULTZ (for herself, Ms. DEAN, Ms. MUCARSEL-POWELL, Ms. SHALALA, Mrs. WATSON COLEMAN, Mr. RYAN, Ms. DELAURO, and Ms. WILSON of Florida) introduced the following bill; which was referred to the Committee on the Judiciary, and in addition to the Committee on Homeland Security, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To grant Members of Congress access to detention facilities,
and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Help Oversee, Manage,
5 and Evaluate Safe Treatment and Ensure Access without
6 Delay Act of 2019” or the “HOMESTEAD Act of 2019”.

1 **SEC. 2. MANDATORY ACCESS TO DETENTION FACILITIES.**

2 (a) IN GENERAL.—A Member of Congress may not
3 be prevented from entering any detention facility for the
4 purpose of conducting oversight.

5 (b) TEMPORARY MODIFICATION.—The head of a de-
6 tention facility may not make any temporary modification
7 at the detention facility in a manner that alters what is
8 observed by a visiting Member of Congress.

9 (c) NO NOTICE REQUIRED.—A Member of Congress
10 shall not be required to provide notice of intent to enter
11 a detention facility for the purpose of conducting over-
12 sight.

13 (d) DETENTION FACILITY DEFINED.—In this sec-
14 tion, the term “detention facility” means any facility—

15 (1) used to detain or otherwise house aliens;
16 and

17 (2) operated by or for—

18 (A) the Department of Homeland Security
19 (including any facility operated by a private
20 contractor with the Department); or

21 (B) the Department of Health and Human
22 Services (including any facility operated by a
23 private contractor with the Department).

○

Ms. DELAURO. Thank you very much. Congressman Burgess.

Mr. BURGESS. Thank you, Chairwoman, and thanks to the ranking member for having this hearing and allowing me to testify today. And I am grateful that the Congress has recognized that we are facing a humanitarian crisis on our Southern border.

The unprecedented surge in the number of unaccompanied children and family units crossing our Southern border this year has stressed a system never designed to handle the current volume. In May, over 144,000 people crossed our Southern border, the highest number since the crisis began in 2014. Over 11,000 of these individuals were unaccompanied alien children.

These children endure terrible conditions to travel across the desert. Sometimes they ride on top of a train to reach our Southern border. They deal with cartels. They deal with coyotes. They deal with gangs. They deal with human traffickers.

When they arrive and they are determined to be an unaccompanied alien child, they are transferred to the care and custody of the Department of Health and Human Services Office of Refugee Resettlement. Secretary Azar, Jonathan Hayes, the Acting Director of ORR, and their teams are doing a good job under trying circumstances for these children, with limited resources and sometimes gross mischaracterizations of individuals.

With a surge in arrivals, Department of Health and Human Services does not have sufficient time to establish permanent licensed shelter beds. So the Department of Health and Human Services must care for these children as they arrive in the hundreds every day.

Influx facilities like Homestead allow the Department of HHS to care for some children and those who are expected to be placed with a sponsor quickly for a shorter period of time. I visited Homestead with several Democratic Members of Congress. The conditions I found, the conditions I saw were comfortable and age appropriate.

Children were provided three meals a day, plus snacks. They were given new clothing, education, medical care, mental health screenings and mental healthcare, outdoor time, and pizza parties. When I heard the comments from other Members of Congress at their press conference after this tour, I couldn't help but wonder if we had visited facilities on different planets, the wording was so different.

This crisis is receiving heightened attention and has caused some Members of Congress to be highly accusatory. Sometimes they do so without visiting the shelters or speaking with the individuals about which they are making the accusations. This exaggeration is inaccurate, unfair, and inappropriate, and it is only making the job of caring for these children more difficult. Members of Congress cannot make such accusations and then demand immediate and unannounced access to the facilities.

Now look, just recently we provided some needed relief in a border supplemental bill, but even that legislation was called a child abuser bill. So let us be very clear. The Office of Refugee Resettlement is doing the job that Congress has asked it to do, and they do not deserve the unfounded accusations that are being leveled against them.

While the Office of Refugee Resettlement takes good care of children to which they are referred, many remain with Customs and Border Protection facilities for too long. The United States Customs and Border Protection facilities are not set up to house children. Placing a child in an Office of Refugee Resettlement operated influx shelter is far preferable to leaving a child for an extended period of time at an overcrowded and ill-equipped Customs and Border Protection facility.

Everyone has an interest in moving these children out of the custody of Homeland Security agencies and into HHS area as quickly as possible. State-licensed and small facilities are the most ideal situation prior to family placement, but when HHS does not have the capacity to accommodate the thousands of minors arriving in these small-scale facilities, it is preferable to move them into an influx facility and out of Customs and Border Protection.

At least this way, they can access medical and legal services and have access to child-appropriate activities and education, rather than having them back up at overcrowded, resource-constrained Border Patrol stations.

I also want to note that the Homeland facility was first opened and operated as a facility in the previous administration. Many of the services have been provided since the previous administration. I do not recall the cries of protest during the previous administration.

And just in my last moments, I do want to let the committee know I have prepared a timeline of all of the different visits I have made over the last 5 years. There are in excess of 10 of those to ORR and Customs and Border Protection facilities. This is not an issue that I take lightly.

But I also want to stress that our words matter, and we have men and women who are on the ground doing a very difficult job that Congress has asked them to do. And Congress will not change the law. So the expectation is the job is going to continue to be difficult.

I want to submit to the record a letter from Jonathan Hayes written to another committee because of the false accusations that were leveled against the men and women of his Department. It makes it very difficult for them to do their job when they were accused in an unfounded way by Members of Congress.

I thank you for the time. I will yield back.

Ms. DELAURO. Thank you both very, very much for coming forward this morning and your remarks.

Mr. BURGESS. May I ask unanimous consent to add these to the record?

Ms. DELAURO. Unanimous consent, so ordered.

[The information follows:]



ADMINISTRATION FOR CHILDREN & FAMILIES

330 C Street, S.W., Washington, DC 20201 | www.acf.hhs.gov

February 28, 2019

Representative Ted Deutch
2447 Rayburn House Office Building
Washington, D.C. 20515

Dear Representative Deutch:

At the February 26th House Judiciary Committee hearing, you stated that ORR created “an environment of systemic sexual assaults by staff on unaccompanied alien children” and went on to conclude that you have seen “thousands of cases of sexual assault, if not by HHS staff, then by staff HHS oversees.” (emphasis added). However, this is unsupported by the data you provided and none of the allegations involve HHS employees. By deliberately or negligently mischaracterizing the data during a televised hearing, you impugned the integrity of hundreds of federal civil servants who, like Commander White, work tirelessly to ensure the well-being of the nearly 50,000 unaccompanied alien children who they have been charged by federal law to protect annually. On behalf of these dedicated employees of HHS assigned to the UAC program, we request that you apologize to these career civil servants for your untoward and unfounded comments. Acknowledging that you were wrong is the moral, decent and right thing to do.

Child safety is our top priority in managing the UAC program. All but one of our care facilities are licensed by the authorizing state residential child care agency, and operate under intense state and federal oversight. Because ORR care facilities diligently track all allegations of a wide range of sexually inappropriate conduct, ranging from name calling or use of vulgar language to more serious claims, the data given to Congress by our agency reflects allegations much broader than just ‘sexual abuse’ (as defined in 34 U.S.C. § 20341 and in ORR regulations at 45 C.F.R. § 411.6), to also include ‘sexual harassment’ (as defined in ORR regulations at 45 C.F.R. § 411.6) and ‘inappropriate sexual behavior’ (a catch-all category for sexual behaviors that do not rise to the level of sexual abuse or sexual harassment).

The total number of sexual conduct allegations reported to ORR decreased in FY2017 (1,069 total) but otherwise has generally remained relatively stable each year (FY2015: 1,000 total, FY2016: 1,226 total, FY2018 (through July): 1,261 total). The vast majority of the allegations reported to ORR are ‘inappropriate sexual behaviors’ involving solely UAC, and not staff or any other adults. Facilities can often resolve these allegations by, for example, counseling the minors about more appropriate behaviors.

More serious allegations rising to the level of ‘sexual abuse’ are reported to both ORR and the Department of Justice (DOJ). Of these, the vast majority involve ‘UAC-on-UAC’ allegations; the distinct minority involve adults. In FY2015, 279 allegations of sexual abuse were reported. Of these, 8.6% (24 instances) involved allegations of facility-staff-on-minor sexual abuse. These metrics fluctuated in subsequent years but remained relatively consistent. In FY2016, ORR and DOJ received 348 allegations of sexual abuse, and 16.1% (56 instances) involved facility-staff-on-minor allegations; in FY2017, ORR and DOJ received 264 allegations of sexual abuse, and 18.6% involved facility-staff-on-minor allegations (49 instances); in FY2018 (through July), ORR and DOJ received 412 allegations of sexual abuse, and 11.9% involved facility-staff-on-minor allegations (49 instances). Thus, the total number of incidents of alleged ‘sexual abuse’ involving facility-staff-on-minor misconduct across a four-year period spanning the previous administration and this administration was 178 out of approximately 182,806 children under



ADMINISTRATION FOR
CHILDREN & FAMILIES

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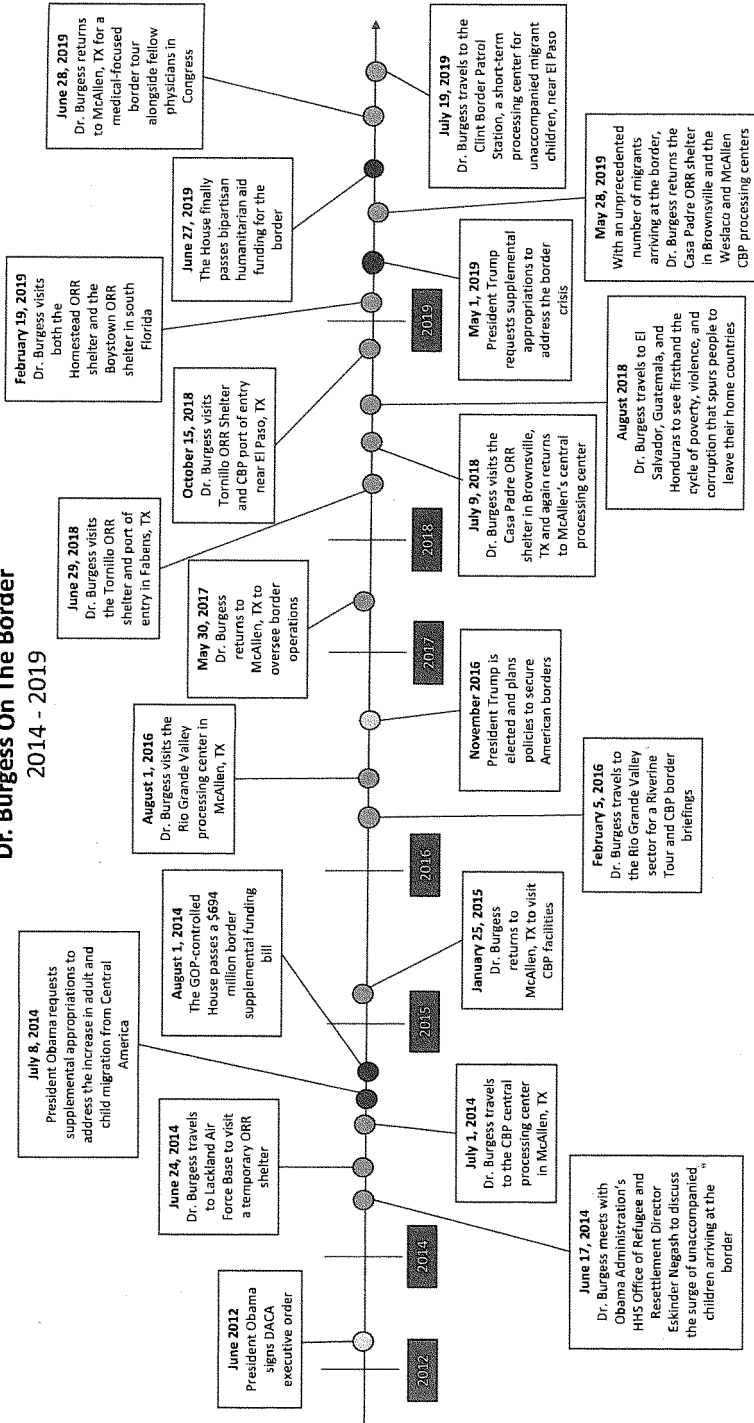
UAC care or about 0.10% of all children placed in ORR custody during that period. None of the allegations involved ORR or other HHS federal staff. These allegations were all fully investigated and remedial action was taken where appropriate.

Your office staff requests an additional briefing from ORR program officials on these allegations. ORR will be happy to meet with you once you correct the hearing record and provide an apology to the dedicated men and women working tirelessly to protect and improve the lives of unaccompanied alien children in our care.

Sincerely,

Jonathan H. Hayes
Acting Director
Office of Refugee Resettlement

Dr. Burgess On The Border 2014 - 2019



Mr. BURGESS. Thank you.

Ms. DELAURO. If I can ask Congresswoman Shalala and Congressman Higgins to take their seats.

Good morning. Let me welcome my colleagues here this morning, and let me introduce Congressman Clay Higgins of Louisiana, who is a member of the Homeland Security Committee, as well as the Committee on Oversight and Reform. And also to introduce Congresswoman Donna Shalala of Florida, a member of the Education and Labor Committee, as well as the Rules Committee. Congresswoman Shalala served as the Secretary of Health and Human Services under President Clinton.

And to both of my colleagues, your full written testimony will be entered into the record, and you are recognized for 5 minutes. Representative Higgins.

Mr. HIGGINS. Thank you, Madam Chair and members of the committee.

I very much appreciate the opportunity to address you today. I was advised that we should share our personal experiences regarding the children that are being processed at our Southern border and the means by which this is happening. This is costing a tremendous amount of American treasure. You men and women are responsible for the effective and efficient management of the treasure that we seize. Therefore, it is appropriate that this is reviewed.

Now I believe it is important that we note, as patriots all regardless of our political affiliation, we are moms and dads and grandmas and grandpas. And we have a compassionate approach to how we care for the children of the world, regardless of where they are or how they arrived here. Yet we have a mission to maintain the sovereignty of our Nation and to stay within the parameters established by our Constitution.

My experience with children that have been through trauma in some manner in life is quite a unique perspective because I was a night shift cop for 8 years during the course of my 12 years as a police officer. And at night is when things go wrong. Mom is home. Dad is home. Hard day, money problems. Frequently alcohol involved. Sometimes drugs. Things go wrong in households right here in America from sea to shining sea. The nightshift cops witness this firsthand.

I have a nickname in Louisiana. I am referred to commonly as "Uncle Clay." This manifested over the course of many years from interacting with children on night shift that have perhaps never had a positive interaction with a police officer. I made it a habit to take and eat with those kids once order had been restored, and I would ask them, "Do you know who I am?" And they would be rather bewildered looking and say no or you are the popa.

I would say, "I want you to think of me as 'Uncle Clay.' We are going to take daddy away for a little while, and we are going to treat him good, and when we bring him back, things are going to be better. And we will always be here for you." Through the years, this grew.

So I went to the border. I have been to the border before. I have brothers and sisters that are thin blue line report to me regularly from the border. Send me texts and emails and videos. I went to

the border this last weekend specifically to look at how kids were handled.

What I witnessed, if our endeavor is to provide compassionate law enforcement under virtually impossible circumstances, then the American men and women of law enforcement on our Southern border have set a stunning example for the world to observe.

With depleted resources and overburdened infrastructures, operating at 200, 300, 400 percent capacity, these men and women, primarily of Hispanic descent—Hispanic origin, virtually all—mostly mothers, fathers, grandmas, and grandpas themselves—they have done their best.

We visited a series of sort of the chronological process by which a child is picked up in the field and processed through in a matter of a couple of days through facilities, one of which had been stood up for the last few months, an 800,000 square-foot facility, the Donna facility in McAllen, Texas. Strictly for processing incoming family units, of course. That includes children. Handled very effectively, incredibly compassionately.

After a life of who knows what horror these family units or children have fled from, they have arrived on American soil, and they are treated well and processed efficiently. And up in HHS, ORR—Office of Refugee Resettlement—the facility I observed had a 6-to-1 ratio of professional social staff that included medical supervision, et cetera.

I noticed that the building was unsecured to an extent regarding exit, and I asked these professionals what stops these kids from leaving? They said they want—they enjoy the structure. First time in their life perhaps they have had some structured environment where they are treated well, fed regularly, have personal hygiene, et cetera.

They had 54 kids in the 60 capacity unit. Their average time there was 32 days, and then they would move to a home, a family home.

So, in summary, my fellow child of God and Republicans and Democrats both, we are all doing our best to deal with the situation. I believe the money, which is your question perhaps, the money that is being invested is being invested quite wisely in the care of children at the border.

We have broken the ice as a bipartisan bicameral Congress regarding funding for the law enforcement professionals and HHS professionals on the border. We should continue to do so and keep in mind that these men and women are doing their very best to maintain the sovereignty of our Nation while, at the same time, their commitment as a compassionate and principled American citizen.

Thank you for allowing me to address your committee today.

Ms. DELAURO. Thank you very much.

Congresswoman Shalala.

Ms. SHALALA. Thank you for holding this hearing to ensure the safety of our children.

I say “our children” because those who are in HHS’s care are our collective responsibility. On the wall of the HHS building, which is named for Hubert Humphrey, is a quote from Humphrey. “The moral test of government is how that government treats those in

the dawn of life, the children.” We are judged, first and foremost, by how we treat our children, and we have a moral obligation to treat these children as we would treat our own.

As someone who has inspected the ORR facility in my district’s backyard—the Homestead facility—as someone who was responsible at one time for ORR, I can confidently say very simply that we are not doing good enough. We must do better.

The children housed at the Homestead facility are between the ages of 13 and 17. Despite their youth, they have already faced unfathomable hardship, including poverty and violence in their home countries and the journey they have made to our country. I have seen the prison-like conditions in which they are kept. They are closely monitored, unable to leave the compound, kept in military camp-like rooms, one of them with up to 150 children per room, and barred from even hugging their friends and siblings.

Some of these children have been forcibly separated from their parents or other relatives or younger siblings without explanation. And what is more, the Homestead facility is for profit. Caliburn has received a no-bid \$300,000,000 contract extension. We are letting a private company make money off of running a detention center for children. We have got to do better.

In June, the Washington Post reported that the administration is canceling English classes, recreation programs, and legal aid for unaccompanied minors in their custody. These are basic services that the administration is legally obligated to provide unaccompanied children who are detained in these facilities. So how did the administration get around this?

Back to the example of Homestead, which is classified as an emergency influx shelter. That means that the children are not protected by the Flores Agreement, which sets limits on how long children can be detained and sets strict standards for conditions in which they can be detained. Because it is located on Federal land, this facility is not covered by State regulations on the treatment of children. These are loopholes that leaves these unaccompanied children vulnerable to the incalculable harms that are preventable.

These children are on their own in every unimaginable way. So I thank the chairwoman supporting my amendment to Labor, HHS that increases funding for legal services, child advocates, and post-release services.

Its passage was a good first step. But again, we have got to do better because these policies are impacting unaccompanied children, and they are impacting children in my community that live near Homestead.

Recently, nearly 1,000 public school children in Miami-Dade took part in a letter writing campaign to the migrant children being detained at Homestead, offering words of hope, love, and solace. My local news station aired a story on the letters. Thirteen-year-old Mattias explained, “It is not fair because if I am an immigrant and I feel accepted, how come other people are being mistreated, held against their will? So I felt like it is time for change. So I decided to write my letters.”

Fourteen-year-old Christian said, “I am an immigrant as well, and I could understand how it would feel to lose your family. That

is something tough to go through. I get that. So I just want to help them.”

Miami-Dade County, where Homestead is located, is 53 percent foreign born, many of them children. So this is affecting my community, both inside and outside the detention center’s walls.

A Miami-Dade Public Schools counselor warned, “I don’t yet believe we realize the scope of the problem that has been created by detaining these children. I do believe that our students become more aware of what is happening at Homestead, and there is a fear factor being played out for our students who do live in the community.” It will be years before we know the full mental health impact of these policies on our children. So this hearing has never been more urgent.

To close, I implore this committee to ask a straightforward question to our colleagues at HHS. What resources are needed to get these children to their sponsors faster? We have got to focus on the outcomes. These children should be in their sponsors’ homes in 2 weeks or a little more, and the sponsors must feel safe to come forward.

If ORR can’t get these children to sponsors within a fair, compassionate timeline, they need to tell us why. But more importantly, they need to tell us precisely what resources they need.

Thank you very much.

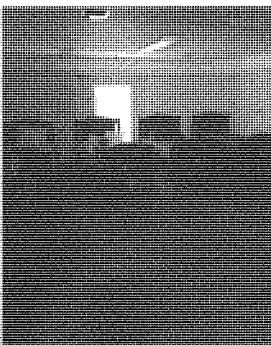
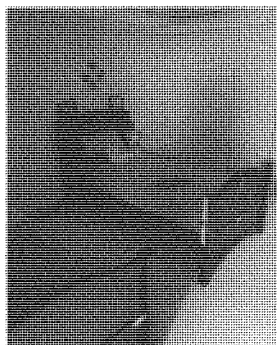
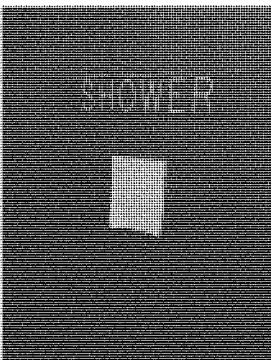
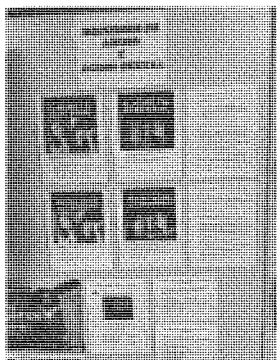
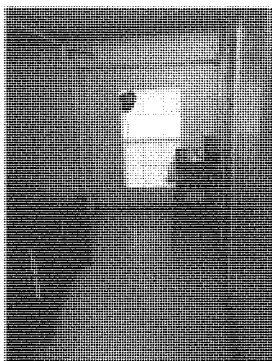
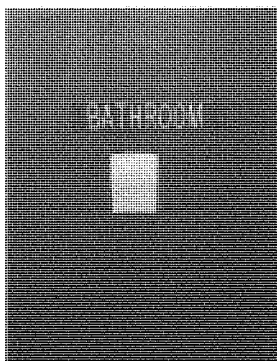
Ms. DELAURO. Thank you. I want to say thank you to both of my colleagues for your testimony and for your concern about what is a very serious issue.

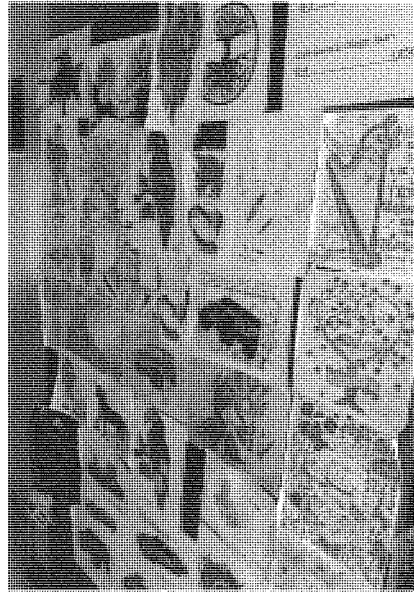
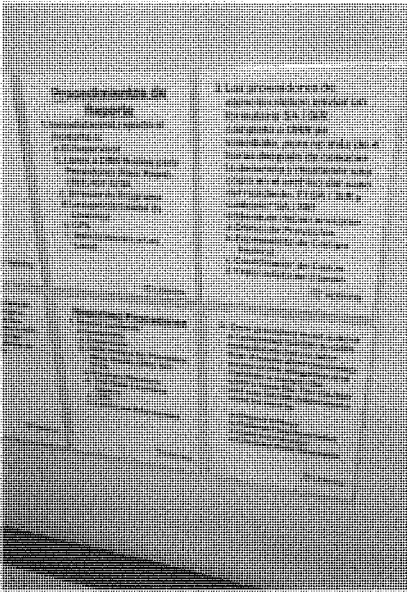
Thank you very much.

Mr. HIGGINS. Madam Chair, I would like to ask, if it is appropriate, unanimous consent to enter into the record some photographs along with my transcribed testimony.

Ms. DELAURO. So ordered.

[The information follows:]





Ms. DELAURO. If we could now have the second panel come forward.

[Pause.]

Ms. DELAURO. Happy to welcome here this morning the Director of the Office of Refugee Resettlement, Director Jonathan Hayes, and the Assistant Secretary for Administration for Children and Families, both from the Department of Health and Human Services, Assistant Secretary Lynn Johnson.

Thank you very, very much for being here this morning, and welcome to you.

To start today's hearing, I would first like to describe what has put us into this crisis. The surge of unaccompanied children at our border is nothing new. It occurred as well in 2014 and in 2016. Without doubt, we have seen the increases this year that have worsened the situation.

Make no mistake, however, that it is administration policies that have brought us to the brink, a crisis created by failed administration policies. In 2017 and 2018, the administration initiated a zero-tolerance policy, which, as a result, separated children from parents, adding to the numbers of unaccompanied children.

The Department of Health and Human Services and the Department of Homeland Security initiated a Memorandum of Agreement using children as bait and scaring sponsors from coming forward by rendering HHS as an immigration enforcement tool. How has the administration done this?

Most chillingly, the administration introduced new bureaucratic delays and onerous fingerprinting requirements on sponsors. They began fingerprinting all members of the household beyond those individuals applying to be sponsored, thereby discouraging sponsors from coming forward, leaving children languishing in Federal custody.

These failed policies strained the capacity of the network of HHS's State-licensed residential shelters for children and led to the opening of emergency influx facilities like Homestead and Tornillo. Influx facilities are unlicensed shelters, essentially warehouses for children. They are not bound by State or Federal standards of care.

As the Appropriations Subcommittee which funds the Department of Health and Human Services, we have been talking about these intentional and harmful policy choices. We hosted a hearing on the UAC program earlier in 2019. We hosted a bipartisan private briefing with the Office of the Inspector General at HHS. And just last week, we visited the influx facility in Homestead, Florida.

Let me say that I was sorry that Ranking Member Cole could not attend because of a prior commitment, as I know he wanted to be there. But we extended the invite to our friends on the other side of the aisle.

On our visit, we confirmed that the Federal Government is using Federal property to skirt Federal standards of care. Why are Federal facilities exempt? The guiding principle of U.S. and international law concerning these children must be the best interest of the child. Both the Flores Agreement and international law say that we should be keeping children for the shortest time and in the least restrictive setting possible.

Visiting Homestead, we saw children under guard. Children have no freedom of movement. They are always, wherever they go, accompanied by a guide. They wear lanyards with barcodes. The bedrooms have no doors. The bathrooms have no doors, only shower curtain liners.

Visiting Homestead, we learned that they have only four physicians, no psychiatrist, and only five certified teachers. We saw the education facility, which is not conducive to learning. The sound of a typical South Florida rainstorm pouring down on this tent was deafening.

The din, the noise was so loud that the congressional delegation was taken to another room to be able to have a quiet conversation. Not an atmosphere which is conducive to learning. Classrooms are structured. Children are silent. The teacher teaches, and children learn. That is not what is happening at Homestead.

What we also discovered was that the education curriculum and the placement are not designed by the Florida Department of Education, in conjunction with the Florida Department of Education, or the Miami-Dade Department of Education, but by the contractor who deals with the tools for education. We were told by some children that they have been there 44 days, 56 days, 60 days when, in fact, they have family members in the United States.

And yet we learned that over 1,000 children were moved to placement with a sponsor in a 2-week period. Let us be clear. This was not a matter of resources. This was a policy decision by ORR. It made us ask if we can move these children this quickly, why were we not moving them all along? Why did we have chaos at the border and children not being able to be moved in the appropriate period of time?

And we found the children are continuing to be separated from family members—aunts, uncles, grandparents—who are their primary caregivers. This is what we heard. That must end, and I am working on legislation to address this.

We still do not know the level of information that is being communicated between the Departments of Health and Human Services and Department of Homeland Security and ICE. We need to be sure that it is not putting the youngsters in jeopardy nor their families. This is a concern for sponsors, who may not be willing to come forward if they are threatened with deportation.

We were shocked to see a checklist outlining the notification process to ICE when a child is just days away from turning 18 years old. The Office of Refugee Resettlement is not an immigration enforcement agency. They should not be mailing ICE 2 weeks out, 1 week out, 24 hours out of a child turning 18, and the child is picked up on their birthday.

And I don't make this up. One of the folks providing us with the tour literally lifted up her hands, and she said, "They are taken out handcuffed." Handcuffed. And where are they going? What has become of these children? We need to know.

The mission of the Office of Refugee Resettlement is to provide care and the expeditious placement for children with sponsors. That is what we are trying to do. That is our job. That is the agency's job.

And yet HHS is clearly not on the same page. They have so obfuscated the goal of this agency that I believe they have lost sight of their goal and their mission.

Secretary Johnson, in my office, you said you wanted to create a “business model.” That is not correct. Nowhere in the mission statement of ORR does it say we should be building the capacity of detaining children for either short periods of time or longer periods of time.

So let me say with the utmost and resolute clarity, we are not going to be setting up an indefinite detention empire. Instead, we must be taking the necessary steps to care for children in the least restrictive possible setting and place them in a safe setting with a family member or sponsor as expeditiously as possible.

To do so, we must be responsibly closing down Homestead and all influx facilities. We need clarity on Carrizo Springs. And I am not interested in us starting up an influx facility at Fort Sill.

Rather than focusing on beds and more beds, which the administration continues to do, we need to be moving to a system that does not require unlicensed influx facilities, and we need to be discharging kids to a safe setting.

Second, we must end the memorandum of agreement between the Department of Health and Human Services and the Department of Homeland Security, which is a deterrent to people who would otherwise be willing to come forward as sponsors.

Let me quote an ORR grantee who says, “We are—” And again, it is a quote. “—using children as bait for immigration enforcement. It is alarming and cruel. And under no circumstances is it justified.” That is the MOA, and it needs to be terminated immediately.

And third, we need to be prioritizing a safe discharge process, as opposed to simply expanding detention capacity. That should be our main goal, as it is the stated mission of ORR.

The administration is now telling us that they want to create the capacity to detain 20,000 children, up from the current capacity of 12,000. Where did that number come from? The peak has been 15,000 children, which occurred last December. And instead of simply creating an unlicensed detention complex, we need detailed plans about a discharge process that gets children in and out of ORR’s care as quickly and as safely as possible.

To close, let me say that Congress has a legal and a moral responsibility to conduct oversight of the UAC program and to ensure that children are being taken care of. Our visit raised more questions than it provided answers and reminded us that our responsibility did not end with the emergency supplemental. It began anew.

In fact, given the Trump administration history on this issue, our responsibility as elected officials and as people is heightened. We cannot allow systematic Government-sanctioned child abuse on our watch.

Now I would like to introduce my colleague from the State of Oklahoma, the ranking member of the committee, Representative Tom Cole, for any opening remarks that he would like to make.

Mr. COLE. Thank you very much, Madam Chair.

And I want to begin by thanking you for this hearing. I think it is a very important hearing and timely. And you have been en-

gaged in this issue from its emergence, and I think you are to be commended for that.

Before I begin, I want to remind everyone watching of the history of the program we are talking about today and the ongoing challenges regarding its implementation. Responsibility for the care of unaccompanied children is relatively new. The duty came to HHS as part of the Homeland Security Act of 2002.

Federal law requires the Department of Homeland Security to transfer to HHS any unauthorized minor not accompanied by a parent or legal guardian. This legal requirement means that when Customs and Border Protection or Immigration and Customs Enforcement apprehend a minor with an uncle, an aunt, grandfather, grandmother, or older brother or sister, the law defines the minor as unaccompanied and requires the transfer of that child to HHS.

I understand there are many who believe these children should remain with the adult relative they are traveling with. However, that is not the law of the United States, and that is not within the purview of HHS to change. That is within the purview of Congress to change, if we choose to do that.

HHS and the Office of Refugee Resettlement, which oversees the Unaccompanied Alien Children Program, does not separate children from their parents. Let me repeat that. HHS does not separate children from their parents and has not done so in the past. HHS is only responsible for the care of children who are unaccompanied, and this is a statutory responsibility given to them by Congress.

I think it is obvious to everyone here that there are significant disagreements between the President and the House majority on matters pertaining to immigration policy, and I know my Democratic colleagues are concerned about the administration's action in this area. But disagreements over the interpretation or implementation of immigration policy fall squarely under the Departments of Justice and Homeland Security. These policy discussions, frankly, are outside our jurisdiction as a subcommittee.

Fiscal pressures associated with large numbers of immigrants at the Southern border is not, as my friend the chairman pointed out, a new phenomenon. In 2014, President Barack Obama requested a supplemental appropriation to address the urgent humanitarian situation on the Southwest border. House Republicans, then in the majority, voted on a bill to address President Obama's request in 24 days.

The majority waited roughly twice as long to give a vote to the request for the humanitarian assistance by the Trump administration. Frankly, in my view, that delay compounded—that delay by Congress compounded the crisis at the border and made things worse, not better.

In 2014, the year of President Obama's supplemental appropriation request, HHS cared for over 57,000 unaccompanied minors, an unprecedented number. By all accounts, in 2019 the number of unaccompanied minors cared for by the Trump administration will likely exceed 60,000, more children than in any prior year on record. This administration inherited the humanitarian crisis on the Southern border, one that has only worsened in recent years.

The Congress recently approved a supplemental funding bill to help alleviate the problem. And the bill included numerous oversights, many based off provisions of the fiscal year 2020 House bill. The bill was by no means a blank check. The funds are welcomed and critically needed, but securing additional beds won't happen overnight.

The unprecedented surge in the number of unaccompanied children and families crossing our Southern border this year has stressed a system never designed to handle the current volume of children. HHS cannot move minors into beds they don't have.

In the meantime, HHS must continue to care for these children as they arrive in the hundreds daily. The U.S. Customs and Border Protection agency facilities are not set up to house children. Everyone has an interest in moving these children out of Customs and Border controlled custody and into HHS custody as quickly as possible, and everyone agrees that State-licensed and small facilities are the most ideal situation.

But when HHS does not have the capacity to accommodate the thousands of minors arriving in these small-scale facilities, it is preferable to move them into influx facilities, where they can at least get medical attention, services targeted toward youth, and have access to child-appropriate activities, rather than having them back up at overcrowded, resource-constrained Border Patrol stations.

I know that my friends at HHS are doing the best they can to bring all facilities up to standards as quickly as possible, and I want to commend them for the difficult work they are performing and note that many of the same challenges were faced by a prior administration. Frankly, HHS has had some successes it doesn't get a lot of credit for.

Somehow in the testimony we heard earlier today, my colleagues missed the fact that Homestead was actually initially used by the Obama administration and that the current provider was chosen initially by the Obama administration. And frankly, the average stay there now, as I understand it, is about 42 to 44 days. We would like it to be quicker, but that compares to about 90 during the Obama administration.

So, again, this is a problem that all of us have had to wrestle with before. I remember very well because I was chairman of this committee in 2014. I remember working with Secretary Burwell at the time on the challenges she had, and Fort Sill was once again being used as a facility.

I want to thank the chairman here—I want to interrupt my testimony and thank the chairman for inviting me to go Homestead. I can assure her, and I know she knows this is true, I would have gone had I not had the commitment. I would have really gone.

I have seen these facilities before, but to be fair, most of them were in 2014. Got scheduled trips coming up to some facilities so I can be up to speed. But from what I can tell and the testimony of the people I talked to, I don't find the conditions dramatically different in 2019 than they were in 2014. I find the crisis eerily similar and the strained resources all too familiar that we put HHS and ORR in a situation to deal with.

So, again, I want to thank the chairwoman for having this hearing. It is an important hearing. I want to thank the witnesses for being here. I am looking forward to your testimony.

And with that, Madam Chair, I yield back my time.

Ms. DELAURO. Thank you very much, Mr. Cole.

Now I would like to recognize the chair of the Appropriations Committee, Congresswoman Nita Lowey.

Mrs. LOWEY. And I want to thank you, Chairwoman DeLauro and Ranking Member Cole, for holding this hearing.

And I want to thank the witnesses in each of the panels for joining us today.

Last week, I, along with Chair DeLauro and several of my colleagues, toured the Homestead influx facility in Florida. We saw firsthand the results of the Trump administration's policies, which directly led to backlogs and the use of massive for-profit influx facilities like Homestead instead of children being with their families.

I am very concerned that companies operating under no-bid contracts are making profits by holding children for months on end, to the detriment of those children and American taxpayers. Children belong with families and loved ones, and facilities like Homestead must be the absolute last resort.

Unfortunately for too many children, prospective sponsors who would care for them in loving homes are faced with a terrible choice—leaving these children in custody or identifying themselves as viable sponsors at the risk of themselves, their family, and their neighbors. Given the administration's goal of stoking fear in immigrant communities, no one is surprised that many sponsors are too frightened to come forward, even with policies this committee has passed to ensure that ICE cannot use data from ORR for deportation.

In fact, before I go on, I want to say that was not clear to me, and perhaps you can elaborate on it, as to whether that information that this facility Homestead had was kept privately within that facility or shared with ICE. We seem to get conflicting information, and I think it is very important that we understand that. And this is what happens when an administration at every turn seeks to divide the country and play to its political base at all costs.

The purpose of today's hearing is to discuss the distinct needs of these children and ensure the Federal Government is abiding by our laws and our values. Ensuring that children receive the proper care includes meeting physical needs like clothing, bathing, nutrition, health screenings, and education. It also means that we treat vulnerable children and families fleeing the war and violence with decency, dignity, and respect.

Upholding these responsibilities is a tall order, especially with this administration. The lives and well-being of thousands upon thousands of children depend, frankly, on your agency fulfilling its responsibility.

I look forward to our discussion today, and I thank you.

Ms. DELAURO. I thank the gentlelady.

And Assistant Secretary Johnson, your full written testimony will be entered into the hearing record, and you are now recognized for 5 minutes for your opening statement.

Thank you.

Ms. JOHNSON. Thank you, Chairwoman DeLauro, Ranking Member Cole, and members of this committee. It is my honor to appear on behalf of the Department of Health and Human Services.

My name is Lynn Johnson. I am the Assistant Secretary of the Administration for Children and Families, and I want to start off by thanking this committee, your staff, for all of your work in passing the recent emergency supplemental appropriation for humanitarian needs.

Before joining this administration, I served as the executive director of Jefferson County Human Services in Colorado overseeing Head Start, workforce programs, career and family services, child welfare, justice services, and community assistance, which included Medicaid.

Prior to this position, I ran my own consulting firm. I served as the chief of staff to Colorado Lieutenant Governor Jane Norton, and policy adviser to Governor Bill Owens. Before joining the Owens administration, I served with the U.S. courts as a probation and parole officer. I carried a specialized caseload of sex offenders and offenders with mental health issues.

ACF administers the Unaccompanied Alien Children Program, which is managed by the Office of Refugee Resettlement. ACF and ORR are not immigration enforcement agencies. We do not set or implement the Nation's immigration enforcement policies, nor do we incarcerate children. ORR provider facilities are not prisons.

Our program is a child welfare agency with a national scope. Let me say that again. We are a child welfare agency focused on providing care and services to an especially vulnerable population. We are obligated under Federal law to accept custody and provide care to any child who another Federal agency determines is unaccompanied.

As Assistant Secretary, I have made it a priority to help ensure that ORR fulfills its responsibility to deliver care while working to discharge children to suitable sponsors as quickly and safely as we can. We know families provide the best care and structure for children, not the Federal Government.

ORR-run facilities, whether licensed or unlicensed, large or small, are always better equipped to serve children than any Border Patrol facility. Therefore, we have made it a priority to obtain as much capacity as possible to help ensure that children are transferred to an ORR care provider facility as quickly as possible.

Unfortunately, the process for obtaining State-licensed bed capacity is time consuming. The State licensing process can take anywhere from 6 to 9 months. Care providers also must hire sufficient staff, meet required supervision ratios under State and Federal laws, conduct background checks on staff.

Staff must attend a variety of pre-employment training, including trauma-informed care, program-specific training, and trainings related to the duties of mandatory reporting. And these are just a few examples of the issues that can add to or complicate the timeframe of bringing these permanent beds onsite. But it is our priority.

Of course, the Federal Government cannot force nonprofit agencies to become ORR care providers, and we are facing increasing

difficulty in attracting new grantees in the current environment. Some of our shelters face near constant protest, and we are under a constant barrage of counterproductive rhetoric. This includes gross factual misstatements by some politicians. For example, comparing ORR facilities to concentration camps, which are then repeated in the media, and then that also scares our children we serve.

I am very concerned that such factual misstatements will ultimately hurt our ability to deliver care. We cannot expect qualified applicants to go through the grant process if success means facing endless political attacks. Many of our grantee's staff are counselors or social workers, and their mission is strictly to care for children.

In our shelters, both permanent and influx, children receive a wide array of services. And you heard this from others before, that they are staying in their own beds, three hot meals a day, snacks, showers, medical and dental care, education, recreation, legal services. And they have asked for more pizza parties and more soccer balls, and we have provided that.

Just like you, I would prefer small, permanent shelters, but I also prefer influx shelters over Border Patrol facilities. My goal and that of our team is for ORR to succeed in providing the very best model of care for children without significant reliance on influx facilities, not just during my tenure as Assistant Secretary, but into the future, regardless of who is in the White House and regardless of who controls Congress.

It is time not to have these crises. It is time to manage this effectively. That being said, I am proud of ORR's UAC program and my staff, and I am thankful for the hard work and diligence of our care providers.

I am equally proud to report that right now, there are no children pending placement over 24 hours in Border Patrol facilities. And despite all of our changes in our testimony, ORR does plan to have enough permanent licensed facilities that we will not need to use influx as of 2020, at the end of 2020.

Thank you again, Chairwoman DeLauro and Ranking Member Cole, because your hard work has helped us make these changes. And I look forward to continuing them into the future and answering your questions.

Thank you.

[The information follows:]



Testimony of

Lynn A. Johnson

Assistant Secretary

Administration for Children and Families

U.S. Department of Health and Human Services

Before the

Committee on Appropriations

Subcommittee on Labor, Health and Human Services,

Education, and Related Agencies

United States House of Representatives

July 24, 2019

Chairwoman DeLauro, Ranking Member Cole, and Members of the Committee, it is my honor to appear on behalf of the Department of Health and Human Services (HHS). My name is Lynn Johnson, I am the Assistant Secretary of the Administration for Children and Families (ACF), a division within HHS. ACF is the nation's preeminent human services agency, and fosters the health and well-being of individuals, families, children, and communities. We provide leadership, partnership, and resources for the compassionate and effective delivery of human services. Part of that work has been to help address the humanitarian crisis at our southern border, and so I want to start off by thanking this committee, and your staff, for all of your work in passing the recent emergency supplemental appropriation to address humanitarian needs.

Before joining this administration, I served as the executive director of Jefferson County Human Services in Colorado, overseeing the county's Head Start program, as well as programs on the workforce, career and family services, child welfare, justice services and community assistance. The highlight of my experience in Jefferson County was building on the Head Start Program. We created a community initiative to end poverty through quality education and opportunities for low income families and children. This initiative enabled them to break the cycles of generational poverty. When I left, the success of this program and the individuals participating was inspiring. Prior to this position, I ran my own consulting firm, which dealt with mental health, high risk youth, developmental disabilities, child welfare and early childhood education. I previously served as the chief of staff to Colorado Lieutenant Governor Jane E. Norton in 2003, and from 1999 to 2002 was a policy advisor to Colorado Governor Bill Owens. Before joining the Owens administration, I served as a senior specialist with the U.S. Courts as a probation and

parole officer. I was responsible for direct supervision of offenders with mental health problems and offenders convicted of sex offenses.

ACF administers more than 60 federally funded human services programs—from child care to child welfare, to child support enforcement and human trafficking. One of these programs is the Unaccompanied Alien Children (UAC) Program, which is managed by the Office of Refugee Resettlement (ORR). Congress moved the UAC program from the former Immigration and Naturalization Service (INS) to ORR when Congress enacted the Homeland Security Act of 2002. ORR provides care and custody to unaccompanied alien children, which are defined by statute as children: who have no lawful immigration status in the United States; who have not attained 18 years of age; and with respect to whom there is no parent or legal guardian in the United States who is available to provide care and physical custody.¹

To be clear, ACF and ORR are not immigration enforcement agencies. We do not set or implement the nation’s immigration enforcement policies. Nor do we incarcerate any children. ORR care provider facilities *are not prisons*.

. ORR’s UAC program *is* a child welfare agency with a national scope, focused on providing care and services to an especially vulnerable population. ORR is obligated under federal law to accept custody and provide care to any child who another federal agency determines is a UAC, with only limited exceptions.² As Assistant Secretary, I have made it a priority to help ensure

¹ 6 U.S.C. §279(g)(2)

² 8 U.S.C. §1232(b)(2)

that ORR fulfills its responsibility to deliver care while working to discharge children to suitable sponsors quickly but safely.

Specifically, over the past six months I have approved or overseen a series of operational directives that have helped reduce the length of stay in ORR facilities by accelerating the safe discharge of children to their sponsors, with priorities given to parents, legal guardians, and close adult relatives. These directives have accelerated discharges by modifying the background check process for sponsorship suitability determinations. Accompanying each directive is a detailed analysis explaining how the change would not compromise the safety of UAC

We have taken action to reduce our length of care because families provide the best care and structure for children, not the federal government. I know this from my firsthand experience managing domestic child welfare systems. ORR's UAC program provides safe and nurturing care for children, but long term congregant care is never the goal of residential programs, especially where there are properly-vetted family members able and willing to provide for the child, and the child does not present a danger to themselves, their family or the community.

While we continually strive to maintain an appropriate length of care, ORR-run facilities—whether licensed or unlicensed, large or small—are always better equipped to serve children than any border patrol facility. Therefore, we have made it a priority to obtain as much capacity as possible, by using both state-licensed beds as well as influx beds, in order to help ensure that children are transferred to an ORR care provider facility as quick as possible.

Unfortunately, the process for obtaining state-licensed bed capacity is time-consuming, so it is not always possible to increase permanent bed capacity to keep pace with sharp increases in referrals, like the ones we've experienced this year. The state licensing process can take anywhere from six to nine months, depending on the physical plant and any alterations a facility may require before it can house children in accordance with state-licensing standards. This process also includes obtaining all necessary permits and Life Safety code inspections by appropriate state and local officials. Care providers also must hire sufficient staff, meeting required supervision ratios under state and federal rules, and conduct background checks on staff. Staff must also attend a variety of pre-employment training including on child trauma, UAC Program specific trainings, and trainings related to the duties of mandatory reporters. These are just a few examples of issues that can add to or complicate the timeline to bring a licensed shelter on board.

Of course, the federal government cannot force non-profit agencies to become ORR care providers, and we are facing increasing difficulty in attracting new grantees in the current environment.

An additional factor that can have a direct effect on our ability to find suitable partners in caring for these minors is the growing amount of misinformation about how the UAC program operates. Some of our shelters face near constant protests, some of which begin peacefully, but at times, have turned chaotic and disruptive to the operations of caring for those minors at the shelter; and we are under a constant barrage of counterproductive rhetoric. This includes gross factual

misstatements by politicians (for example, comparing ORR facilities to concentration camps) which are then repeated in the media.

I am very concerned that such factual misstatements will cause additional trauma and fear to UAC and scare off potential grantees, which will ultimately hurt ORR's ability to deliver care. To understand this concern, you must first understand our typical process for competing grants. We solicit funding opportunity announcements (FOAs) publicly, but are beholden to only those applicants who choose to apply for an award. The applicants are then evaluated against the announcement and competitively scored prior to a decision to award a grant. Once a grant is awarded, the new grantee must appropriately staff the facility (including going through requisite training and background check requirements); obtain the necessary permits and licenses to operate; and other paperwork requirements before opening their doors to receive children. We cannot expect qualified not-for-profit applicants to go through the arduous grant application process if success means facing endless political attacks, without regard to the challenges inherent in caring for the UAC population, or the quality of the care provided.

Like the state licensing process, the number of children arriving at the border is outside the control of HHS. Migration numbers may vary considerably one year (or month) to the next and are largely unpredictable. A phenomenon that began in FY 2012 was the sudden mass migration of children and families from Central America to the United States border. In the years prior to FY 2012, roughly 6,000-7,000 UAC were referred to ORR each year. In FY 2012, that number rose to over 12,000. These numbers jumped dramatically in FY 2014, to approximately 57,500 and again in FY2016 to over 59,000. This fiscal year has seen another dramatic increase in the

number of referrals. We have surpassed the historic record set in FY 2016, with more than 61,000 UAC referrals and counting, and we still have over two months to go before the end of FY 2019. Unpredictable and dramatic fluctuations in referrals of UAC are inherently challenging to manage, and the challenge is compounded by the lead time required to open a state-licensed facility.

In instances where we must bring on additional capacity quickly, we rely on influx care facilities to supplement our state-licensed permanent capacity and help ensure that we can place children in ORR care from CBP custody as expeditiously as possible. Though influx facilities are often brought online before being able to meet state licensing, they are undoubtedly a safe, quality environment for UACs in our care. One such facility, originally identified and funded under President Obama's administration in December 2015 to address a migration surge, is the Homestead Influx Care Facility (which many on this subcommittee have visited). This facility has served more than 23,000 children since it opened. Without Homestead, thousands more children would have been remained at CBP facilities on the border, which are not designed to serve the needs of unaccompanied alien children, for extended periods of time, worsening this crisis.

Many have raised concerns about Homestead based on incorrect information. For instance, we've heard inaccurate statements that the Homestead facility is unlawfully holding children beyond 20 days as mandated by the *Flores* Settlement Agreement (FSA). The "20 day rule," however, is applied to ICE family residential centers. It does *not* apply to any ORR facilities, which is a good thing. ORR may discharge a child only to a suitable sponsor. If there is no

suitable sponsor, then ORR cannot lawfully discharge the child on his or her own recognizance.³ More importantly, discharge to an unsuitable sponsor would endanger the child.

The truth is that the length of stay for children placed at Homestead is on average shorter than that of children in the rest of our network. Children placed at Homestead have an average length of stay of 36 days. While most children who enter an ORR care provider facility are likely to remain there for no longer than 45 days before ultimately being released, they will receive a wide array of services during their stay. More generally, ORR has a policy in effect that ensures that UAC do not remain in influx facilities for longer than 90 days (with limited exceptions). Those services include (but are not limited to): basic shelter and their own bed, adequate food (three hot meals a day plus snacks), daily showers, access to toilets, personal grooming items and clothing; weekly visits with clinicians (and more if needed); medical and dental care, including vaccinations in accordance with CDC recommendations; group counseling; case management services – including family reunification services; education services; acculturation and adaptation services; time for recreation and leisure (beyond just television); and legal services (including information about the child’s rights; legal screenings; and in some instances government funded representation in immigration court).

As ORR brings more permanent, state-licensed capacity online, ORR will stop placing children at influx care facilities. Once sufficient capacity is available, children who have not yet been released from Homestead (or another influx care facility) will be transferred to permanent, licensed beds. As of July 3rd, ORR has stopped new placements at Homestead.

³ 6 U.S.C. §279(b)(2)(B)

Ultimately, I envision a system where ORR is able to support enough permanent capacity that influx care facilities are rarely needed, if ever. My goal and that of our team is for ORR to succeed in providing the very best model of care for children, without significant reliance on influx facilities – not just during my tenure as Assistant Secretary, but into the future, regardless of who is in the White House and who controls Congress. I want a business model to efficiently run ORR during surges and during times of calm. This is my priority. It is time to stop reacting to crises and move to a new normal for this program. Politics has no place when it comes to child safety and their best interest – these are matters of shared concern across party lines.

That being said, I am proud of the federal career staff who operate ORR's UAC program. And I am thankful for the hard work and diligence our care provider grantees and contractors who provide expert services and facilitate the safe release of children to their families under the direction of our federal career staff.

I am equally proud to report that based on our ramping up of additional capacity, the actions that we took to reduce length of care, and the downward trend of recent referral numbers, there are no children pending placement over 72 hours in border patrol facilities.⁴ Despite the challenges noted in my testimony, ORR plans to have up to 20,000 licensed beds available by the end of 2020.

⁴ There are case by case exceptions for children who may be unfit to travel are in the care of a hospital or medical provider while still under DHS custody.

Thank you again, Chairwoman DeLauro and Ranking Member Cole, for your hard work to help make this happen – the supplemental funding is helping address a continuing crisis at our southern border, and is ensuring that vulnerable children are properly placed with HHS.

I look forward to answering your questions.

Ms. DELAURO. Thank you very much, Secretary.

And Director Hayes, your full testimony will be entered into the hearing record. You are recognized for 5 minutes for your opening statement.

Thank you.

Mr. HAYES. Chairwoman DeLauro, Ranking Member Cole, and members of the committee, it is my honor to appear before you on behalf of the Department of Health and Human Services.

My name is Jonathan Hayes, and as the Director of the Office of Refugee Resettlement, I manage the Unaccompanied Alien Children Program. I became the permanent Director earlier this year, and it is a privilege to serve in this role.

I am continually impressed with the level of commitment and professionalism that I see in the ORR career staff and our grantees on a daily basis, who carry out round-the-clock operations in service of some of the world's most vulnerable children. I have visited nearly 50 UAC care providers across the United States over the last year so that I can see firsthand the quality of care provided to these children.

Prior to my time at ORR, I worked for two congressional Members for about 8 years. That experience provided me with firsthand knowledge of the important oversight role that you and your staff have to ensure that Federal programs operate successfully. I am here today to report on the current state of ORR's influx operations during this unprecedented time of high arrival of UAC, including the conditions, services, and standards at our temporary influx care shelters.

I would also like to express the Department's appreciation and gratitude to Congress for passing the emergency humanitarian aid package. Immediately upon enactment of the supplemental appropriation, we restored the full range of services for UAC, including those that we were unable to provide during the anticipated deficiency due to appropriations laws limitations.

HHS operates nearly 170 State-licensed care provider shelters and programs, which include group homes, long-term therapeutic or transitional foster care, residential treatment centers, staff secure and secure facilities and shelters. Our facilities provide housing, nutrition, routine medical care, mental health services, educational services, and recreational activities such as arts and sports, services that are very similar to the domestic child welfare system.

Grantees operate the facilities, which are licensed by the State authorities responsible for regulating residential childcare facilities. While ORR's temporary influx facilities are not required to obtain State licensure, children there generally receive the same level of care and services to UAC in State-licensed facilities.

We recognize that many of these children have experienced traumatic childhood events and that migration and displacement can cause ongoing stress. Care providers are especially trained in techniques for child-friendly and trauma-informed interviewing, assessment, and observation and deliver services that are sensitive to the age, culture, native language, and needs of each child.

Clinicians are able to do crisis intervention and group and individual counseling sessions. If a child is found to have a mental

health need that cannot be addressed at any of our care facilities, we will transfer them to a more appropriate setting.

The number of UAC entering the United States during this fiscal year has risen to levels we have never seen before. As of July 15th, the Department of Homeland Security has referred more than 61,000 unaccompanied alien children to us, the highest number in the program's history. By comparison, HHS received 59,170 referrals in fiscal year 2016, the previous highest number of annual referrals on record.

HHS currently has about 10,000 children in our care, though this number fluctuates on a daily basis. As of June, the average length of time that a child stays in HHS's custody is approximately 42 days, which is a dramatic decrease of 53 percent from late November 2018, when the average length of care was about 90 days.

During my tenure at ORR, we have issued four operational directives and revised our policies and procedures with the specific aim of a more efficient and safe release of UAC to sponsors. It is the expressed desire and goal of both the political and career leadership of ORR to expand our capacity in such a manner that as many children as possible can be placed into a permanent State-licensed facility or transitional foster care while their sponsorship suitability determinations or immigration cases are adjudicated in the event there is no sponsor available.

By December 31 2020, we anticipate that we will have increased permanent State-licensed shelters, including foster care, of up to a total of 20,000 beds, which almost doubles current permanent capacity. In the short term, HHS aims to have about 3,000 additional temporary beds available this fiscal year at influx care facilities in anticipation of continued high arrivals at the Southern border so that UAC do not remain in Border Patrol stations, which are not designed or equipped to care for children.

In conclusion, my top priority and that of my team is to ensure the safety and well-being of children who are placed temporarily in HHS's care and custody as we work to quickly and safely release them to suitable sponsors.

Thank you for your support of the UAC program and the opportunity to discuss our important work. I will be happy to answer any questions that you may have.

Thank you again, Madam Chairman and Ranking Member Cole.
[The information follows:]



Testimony of

Jonathan H. Hayes

Director

Office of Refugee Resettlement

Administration for Children and Families

U.S. Department of Health and Human Services

Before the

Committee on Appropriations

Subcommittee on Labor, Health and Human Services,

Education, and Related Agencies

United States House of Representatives

July 24, 2019

Chairwoman DeLauro, Ranking Member Cole, and Members of the Committee, it is my honor to appear before this subcommittee, on behalf of the Department of Health and Human Services (HHS). My name is Jonathan Hayes. I am the Director of the Office of Refugee Resettlement (ORR) and I manage the Unaccompanied Alien Children (UAC) Program.

I became the permanent director earlier this year, and it is a privilege to serve in this role alongside the ORR career staff. I am continually impressed with the level of commitment and professionalism I see in the ORR career staff and our grantees on a daily basis. The culture of leadership within ORR directly impacts our day-to-day operations and goals, as well as the staff who carry out our round-the-clock operations in service of some of the world's most vulnerable children. I have visited nearly 50 UAC care provider shelters across the United States over the last year so that I could see firsthand the quality of care that ORR staff and grantees provide to the unaccompanied alien children and to hear directly the perspectives and input from our teams in the field, so I can better understand ways to improve our services and overall mission.

My strong desire is to ensure the safety and well-being of the children in our care in a manner that is consistent with the law and empowers the career professionals and senior staff at ORR. As the Director of ORR, I am committed to making decisions that are in the best interest of each child in ORR's care and custody.

Prior to my time at ORR, I worked for two Members of the U.S. House of Representatives for approximately eight years. That experience provides me with firsthand knowledge of the

important role that you and your staff members have in ensuring federal programs operate successfully.

UAC Program Overview

I am here today to report on the current state of ORR's influx operations during this unprecedented time of high arrivals of UAC, including conditions at our temporary influx care facilities, as well as influx service provision and standards. I will also provide Congress with details of the Department's plan on how it will spend the \$2.88 billion from the Emergency Supplemental Appropriations for Humanitarian Assistance and Security at the Southern Border Act.

I would like to first express the Department's appreciation and gratitude to Congress for passing the emergency humanitarian aid package. Immediately upon enactment of the supplemental appropriations, we restored the full range of services for UAC, including those that we were unable to provide during the anticipated deficiency due to appropriations law limitations.

The Homeland Security Act of 2002 (HSA) and the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA), as amended, govern the UAC program. So do certain provisions of the Flores Settlement Agreement (FSA). As defined by the HSA, if a child under the age of 18 with no lawful immigration status is apprehended by another federal agency, and no parent or legal guardian is available in the United States to provide care and custody of the child, then the apprehending agency may determine that the child is a UAC and transfer them to ORR for care and custody.

ORR does not apprehend migrants at the border or enforce the immigration laws. The Department of Homeland Security (DHS) and the Department of Justice (DOJ) perform those functions.

The number of UAC entering the United States during this fiscal year has risen to levels we have never before seen. As of July 15, DHS has referred more than 61,000 UAC to us – the highest number in the program’s history. By comparison, HHS received 59,170 referrals in FY 2016 – the previous highest number of *annual* referrals on record.

HHS currently has less than 11,000 children in our care, though this number fluctuates on a daily basis. The number of children in our care is down from a recent high of over 13,700 just last month; this decline is due to decrease in daily referrals over the last few weeks, and ORR’s ability to maintain a steady high discharge rate of UAC placement with sponsors. As of June, the average length of time that a child stays in HHS’ custody is approximately 42 days, which is a dramatic decrease of 53 percent from late November 2018, when the average length of care was 90 days. During my tenure at ORR, we have issued four operational directives and revised our policies and procedures with the specific aim of a more efficient and safe release of UAC from our care and custody.

HHS operates nearly 170 state-licensed care provider facilities and programs. These care providers include group homes; long-term, therapeutic, or transitional foster care; residential treatment centers; staff-secure and secure facilities, and shelters. Our facilities provide housing, nutrition, routine medical care, mental health services, educational services, and recreational activities such as arts and sports – services that are similar to the domestic child welfare system. Grantees operate

the facilities, which are licensed by the state authorities responsible for regulating residential child care facilities. And while ORR's temporary hard sided influx care facilities are not required to obtain state licensure, children who reside at these locations generally receive the same level of care and services to UAC as a state-licensed facility.

The UAC program bed capacity has expanded and contracted over the years, driven by fluctuations in the number of UAC referred to HHS and the average time children remain in ORR care.

To respond to these fluctuations, HHS has developed processes for bringing both permanent and temporary UAC housing capacity online as needed. HHS has a bed capacity framework with grant and contract mechanisms that provide standard permanent bed capacity, with the ability to add temporary beds. That arrangement helps HHS to accommodate changing flows in the number of referred UAC.

HHS cares for all children until they are released to a suitable sponsor, which is usually a parent or close relative, while they await immigration proceedings. Children may also leave HHS' care if they return to their home countries following an immigration judge's order of removal, turn 18 years of age, or gain legal immigration status.

After HHS releases children and youth from its custody to a sponsor, we offer case management services to those who would benefit from ongoing assistance by a social service agency. Post-release case management services are offered by a network of ORR-funded non-profit service providers. ORR encourages the use of evidence-based child welfare practices that are culturally-

and linguistically-appropriate to the unique needs of each individual and are rooted in a trauma-informed approach. Providers focus on helping released children and youth find and access education, medical and behavioral health care, legal services, community programming, and more. Providers may also offer intensive case management to children and their families if they need support for specific challenges.

These services are not mandatory and released minors and their sponsors may choose to participate or not in these services. Once UAC are released to sponsors, they are no longer in the custody of ORR, and ORR does not have legal responsibility for them.

State of the UAC Program

Licensed Care Provider Facilities

It is the expressed desire and goal of the political and career leadership of ORR to expand our capacity in such a manner that as many children as possible are placed into permanent state-licensed facilities or transitional foster care while their sponsorship suitability determinations or immigration cases are adjudicated (in the event there is no sponsor available).

A minimum of \$866 million of the emergency supplemental funding was provided to increase licensed shelters' capacity – both for new and existing shelters. ORR does expect to exceed this minimum budget requirement. We are working with HHS' Administration on Children, Youth, and Families, as well as non-governmental organizations to leverage state child welfare providers and their provider networks to expand our own network of community-based residential care.

By December 31, 2020, we anticipate that we will have increased permanent, state-licensed shelters (including foster care) to up to a total of 20,000, which almost doubles current permanent capacity. These beds will be funded by a combination of the supplemental funding as well as discretionary funds requested in the President's 2020 Budget. This addition will provide HHS with a necessary supply of permanent, state-licensed beds so that we will not need to place UAC in temporary influx sites.

It takes approximately six to nine months to open new licensed facilities. The start-up process includes the grant making process; retro-fitting the facility to meet specific physical plant requirements for licensed facilities; licensing of the facility by the state; and recruiting, vetting, hiring, and training of staff, among other activities. I am happy to report that our most recent funding opportunity announcement – which closed in May – is leading to new grant awards that will support approximately 3000 more permanent state-licensed beds.

Influx Care Provider Facilities

Some care provider facilities work solely with populations of children who need specialized care including pregnant or parenting girls, infants and small children, and those with mental health conditions. This limits the availability of permanent state-licensed bed space for other children during influxes.

The supplemental appropriations allow \$1.9 billion for general purposes, and HHS estimates that less than \$100 million of this funding will be spent to support influx operations.

In the short-term, HHS aims to have up to 3,000 additional temporary beds available this fiscal year at influx care facilities in anticipation of continued high arrivals at the southern border, so that UAC do not remain in U.S. Border Patrol stations, which are not designed or equipped to care for children.

Up to 1,600 temporary beds will be set up at Fort Sill in Oklahoma, which is the only Department of Defense (DoD) facility being prepared to temporarily house UAC in hard-sided structures. HHS does not use DoD funds for UAC influx operations.

HHS used Fort Sill in 2014 as a temporary influx site, and again chose this location based on a number of factors relevant to child welfare, which included size, types of housing structures, and time considerations. HHS was given close to 30 DoD properties to assess for suitability to temporarily house children in our care. After a careful review, we identified only eight that could potentially serve as an influx site.

I would like to note that among these eight facilities, certain ones did have soft-sided structures for living quarters. However, HHS seeks to limit the use of soft-sided structures except as a last resort to prevent children from lengthy stays in U.S. Border Patrol stations. After consulting with the DoD, three of the military facilities were potentially prepared to house UAC on site in hard-

sided structures, and then two of those facilities were later removed as options. Fort Sill was therefore our only viable option.

This temporary site will be used during hurricane season in the event that HHS needs to evacuate children and staff from our temporary influx site in Homestead, Florida; to prevent backups of UAC in U.S. Border Patrol stations; or to address any other emergent issues that could cause a temporary inability to use one of our regular shelters.

HHS is also in the process of setting up 1,400 temporary beds in Carrizo Springs, Texas. HHS has re-engineered the site, which was formerly a lodging facility for oil and gas workers, so that children are being sheltered in renovated hard-sided structures, while semi-permanent soft-sided structures are being used for support operations.

HHS operates a temporary influx care facility, in Homestead, Florida, which has been in use, on-and-off, since 2016. Children at Homestead live in hard-sided dormitories, have access to dining halls, educational classrooms, indoor and outdoor recreational spaces and fields, and on-site medical facilities.

HHS has detailed policies for when children can be sheltered at a temporary influx care facility. The minor must be a youth between 13 and 17 years of age; have no known special medical or behavioral health conditions; have no accompanying siblings age 12 years or younger; and be able to be discharged to a sponsor quickly – among other considerations.

HHS strives to provide a quality of care at temporary influx care facilities that is parallel to our state-licensed programs. Children in these facilities can participate in recreational activities and religious services appropriate to the child's faith, and receive case management, on-site education, medical care, legal services, and counseling.

We recognize that many of these children have experienced traumatic childhood events and that migration and displacement can cause ongoing stress. On-site care providers are specially trained in techniques for child-friendly and trauma-informed interviewing, assessment and observation, and deliver services that are sensitive to the age, culture, native language, and needs of each child. This includes clinicians, who are able to do crisis intervention, group and individual counseling sessions, and support children as they make what are often emotionally difficult phone calls to their families. If a child is found to have a mental health need that cannot be addressed at the care facility, we will transfer them to a more appropriate setting.

While children at our temporary influx sites do not attend local schools, classes are built into the daily schedule, and instructors are bilingual.

Legal services staff provide children in our care with Know-Your-Rights presentations in the minor's native language within seven to 10 days of referral to ORR, a Legal Resource Guide, and legal screenings that assess a child's background, journey into the United States, family, and history of persecution, violence, and abuse.

HHS is the primary regulator of the temporary influx care facilities and is responsible for their oversight, operations, physical plant conditions, and service provision. While states do not license or monitor influx care facilities, they operate in accordance with the Flores Settlement Agreement, the Homeland Security Act of 2002, the Trafficking Victims Protection Reauthorization Act of 2008, the Interim Final Rule on Standards to Prevent, Detect, and Respond to Sexual Abuse and Sexual Harassment Involving Unaccompanied Alien Children, and ORR policy and procedures.

HHS monitors temporary influx care facilities through assigned Project Officers, Federal Field Specialists, Program Monitors, and an Abuse Review Team, and all have the authority to issue corrective actions if needed to ensure the safety and wellbeing of all children in HHS's care.

As required under the supplemental appropriations package, HHS will ensure "influx shelters are only used as a last resort, meet child welfare standards, and include frequent monitoring;" provide a "15 day notification prior to opening an influx facility;" and "ensure, when feasible, certain children are not placed at influx facilities, including children who would be expected to be there for longer than 30 days."

Services to Children

A minimum of \$100 million was provided to support legal services, child advocates, and post-release services. HHS does expect to exceed this minimum budget allowance, however. HHS will use the supplemental appropriation to fund the expansion of its legal services contracts to accommodate influx capacity, new state-licensed bed capacity, and to continue legal services into

fiscal year (FY) 2020. The minimum legal services required by statute and the Flores Settlement Agreement are a notice of rights and information about pro bono legal assistance. ORR legal services contracts include this, as well as legal screening and legal representation for children who have immigration cases initiated while in ORR custody.

Case Management and Care Coordination

HHS plans to spend \$19 million of the supplemental appropriation for case management and care coordination, which includes hiring an additional 20 Federal staff for field operations. This amount exceeds the minimum required in the supplemental appropriations bill.

Strategic Improvements

HHS plans to spend \$4 million to hire project officers and program monitors, and for the development of a UAC discharge rate improvement plan. This amount exceeds the minimum required in the supplemental appropriations bill.

Office of Inspector General (OIG) Oversight

Five million dollars will be transferred to OIG for oversight of the UAC Program. We look forward to continuing to work with the OIG as they provide us with valuable oversight and evaluation of our program.

Program Administration

HHS will spend up to \$25 million from the supplemental appropriation to extend and expand the contract staff support and modernize the UAC Portal, which is ORR's online case management platform that contains detailed information on each child in care, as well as guidance, procedures, trainings, field guidance, sponsor handbook, and more.

Conclusion

The UAC Program provides care and services to children every day and our work is driven by child welfare principles. HHS is quickly expanding its state-licensed network of shelters to ensure that it can keep pace with the humanitarian crisis at the U.S.-Mexico border. Based on the anticipated growth, HHS expects its need for additional bed capacity to continue, despite placing children with sponsors at historically high rates over recent weeks. Given the unpredictable nature of migration, HHS must ensure it has sufficient capacity to address needs as they emerge.

My top priority and that of my team is to ensure the safety and well-being of the children who are placed temporarily in HHS custody as we work to quickly and safely release them to suitable sponsors. HHS is also working with our colleagues at DHS and DOJ to ensure that we have the information necessary to safely and quickly release children from HHS custody.

Thank you for your support of the UAC Program and the opportunity to discuss our important work. I will be happy to answer any questions you may have.

Ms. DELAURO. Thank you very much.

Let me make one point of clarification, and I say this to my friend and my colleague Ranking Member Cole. In the Obama administration, the turnover was 35 days. It was 90 days last year, as the Director has pointed out.

Director Hayes, in your testimony, you note that children generally receive the same level of care and services as children at a State-licensed facility. Quite frankly, not just myself, but many others—many people on this dais—and folks over and over again in recent weeks and months have noted that these children are not receiving the same standards of care.

So my priority is to responsibly shut down Homestead to eliminate the use of facilities that are not State-licensed. When do you intend to close Homestead? Under what circumstances, if any, would you choose to extend the Homestead contract currently in place through November 30th?

I need you to move quickly as well because we only have 5-minute periods of time. So thank you.

Mr. HAYES. Yes, ma'am, Madam Chair. I just want to reiterate I, too, share your commitment to only utilize influx shelters when absolutely necessary, and we want to see each and every child, as we can, into a permanent State-licensed facility.

Ms. DELAURO. When do you plan to close Homeland—Homestead?

Mr. HAYES. Homestead, the influx shelter, ma'am, we are working as quickly and safely as we can right now to discharge the children that are there to appropriate sponsors. As noted in some of the opening statements, and that we—

Ms. DELAURO. So you are moving toward closing down Homestead in the same way Tornillo was shut down. But shutting down Homestead as soon as possible?

Mr. HAYES. Our team is working without delay to safely and quickly move the children out of Homestead at this moment. We have seen very safe and significant numbers, as we referenced on the CODEL, yes, ma'am.

Ms. DELAURO. And it will be shut down then?

Mr. HAYES. I am not going to commit to actually closing down the shelter at this time, but it is my desire to move the children at Homestead right now out as quick as possible, yes, ma'am.

Ms. DELAURO. Okay. And by the way, we have asked for a copy of the Homestead contract. So we really need to know when you are going to share that with the subcommittee.

Mr. HAYES. I will be happy to get with the team and make sure that it is back to you just as soon as possible, ma'am.

Ms. DELAURO. The Homestead contract goes through the 30th of November. What are the circumstances in which you would intend to extend it? Are you planning to extend it?

Mr. HAYES. I am in constant coordination with both my planning and logistics team, my Deputy Director of the Unaccompanied Children Operations at ORR, to ensure that we have as much capacity as possible in order to move children as quickly as we can from Border Patrol stations into our care. It would only be used—

Ms. DELAURO. Well, you are moving pretty quickly.

Mr. HAYES. We are, yes, ma'am.

Ms. DELAURO. When you have done in a month's time, it was about 1,600, which again makes us all believe as to wonder why we are not moving. In which case, I don't know, how many do you have at Homestead right now?

Mr. HAYES. Ma'am, as of this morning, we have 894, as of 7:00 this morning.

Ms. DELAURO. You had 1,300 when we were there, 1,309, to be exact.

Mr. HAYES. Yes, ma'am.

Ms. DELAURO. So you are moving. So we could move out several hundred kids and really be done with this facility and this warehousing.

Mr. HAYES. My commitment to you, ma'am, is that we are seeking to move the children out of Homestead as quick as possible into either sponsored homes—

Ms. DELAURO. Let me talk about discharge rates and the impact of the Memorandum of Agreement. Operational directives ORR issued December have helped to expedite, without question, the discharge of children from ORR's care. They were only necessary because, because of the Memorandum of Agreement.

Director Hayes, you noted that career staff proposed each of the operational directives that have enabled ORR to place children with sponsors more expeditiously. Question—and I need a yes or no—what about the MOA? Did career staff recommend expanding fingerprinting requirements to all adults living in a sponsor's household? Yes or no.

Mr. HAYES. Ma'am, that was before my time at ORR. So I cannot—I would be speculating if I answered that question.

Ms. DELAURO. Or sharing information on sponsors with ICE for immigration and enforcement purposes, which is ongoing. Is that coming from staff? Yes or no.

Mr. HAYES. Ma'am, the Memorandum of Agreement was set in place before my time in the Office of Refugee Resettlement. I cannot speak to the discussions or recommendations of career staff prior to my time at ORR.

Ms. DELAURO. Okay. So, in fact, we have no—if you tell me that the operational directives that you are now abiding by, which went through to December and March and June, et cetera, that came from your staff folks, not from—and prior to that, you don't have any knowledge of where those—the policy came from?

Mr. HAYES. That is correct. And I will say that I—

Ms. DELAURO. You were working at the time for the—as I understand it, your job was as an Assistant or Deputy to the prior Director. It seems unconscionable to me that you would not know what the directives are, but let me move to Assistant Secretary Johnson.

Have ACF and ORR discussed the potential impacts that rescinding the MOA would have on discharge rates? Yes or no.

Ms. JOHNSON. No, we did not specifically talk about that.

Ms. DELAURO. You haven't? If not, will you look into for us how this change could expedite the release of children?

Ms. JOHNSON. Yes. I will look at that.

Ms. DELAURO. Thank you. I just want to note before I conclude that the written testimony from a witness on our next panel, Krish O'Mara Vignarajah, includes data showing the chilling effect of the

MOA on the willingness of sponsors to come forward. The number of sponsors who backed out of the process increased sixfold after the MOA was implemented.

As I have said in the past, HHS needs to terminate the MOA. Do you agree? Both. Go ahead. Do you agree? Yes or no.

Ms. JOHNSON. Congresswoman DeLauro, we agree that we have got to take these operational directives and make the changes that—

Ms. DELAURO. Yes or no, should we terminate the MOA?

Ms. JOHNSON. Yes, we should.

Ms. DELAURO. Director, yes or no, should we terminate the MOA?

Mr. HAYES. I think the decisions that we made with the operational directives show that that is the path we want to go on, ma'am.

Ms. DELAURO. Should we discontinue the transfer of information as it currently is because there is and should we discontinue the MOA? Yes or no. You direct this operation. You should know whether or not you want to keep this in place.

Mr. HAYES. Ma'am, I think if you look at each of the four operational directives—

Ms. DELAURO. So you are not going to answer the question?

Mr. HAYES. I am not going to speak specifically to the MOA, but I do support the four operational directives in order to expedite the release of children to properly vetted sponsors. I want to see the children back with their families.

Ms. DELAURO. I am going to take this as that you want to continue the MOA and its current destructive effect on discharging students.

Congressman Cole.

Mr. COLE. Thank you very much, Madam Chairman.

We are talking about Homestead. Let us talk a little bit more about it. Mr. Hayes, can you tell me under what administration Homestead was first opened and operated as a facility to house and care for unaccompanied minors?

Mr. HAYES. Yes, sir. Homestead was chosen and the contractor provided in December of 2015 under the Obama administration.

Mr. COLE. And thank you. And the for-profit contractor responsible for comprehensive shelter services, were they also selected by the previous administration?

Mr. HAYES. Yes, sir. They were.

Mr. COLE. Okay. And during that time, was there any calls that you are aware of for closure of Homestead or for dismissal of that particular contractor?

Mr. HAYES. None that I am aware of, sir.

Mr. COLE. Okay. And I think that is important to establish. There is a lot of continuity here.

Let me ask this as well. We have a lot of Members—I have dealt with this at Fort Sill myself—that would like to show up at facilities unannounced and have immediate right of inspection. And there is a case to be made for that, but I also know there is a whole series of legal challenges and problems when that happens.

And I know how disruptive it can be. I saw a case where a member of my own delegation did exactly that, was denied entrance, ap-

propriately so, in my viewpoint. It was actually on a military facility. He was there for other purposes and went over without telling anybody and started demanding to go.

So what are some of the problems—and I address this to both of you. Maybe I would start with you, Secretary Johnson. What are some of the problems that happen if Members don't notify. You don't set up a procedure to actually come and visit.

Ms. JOHNSON. Thank you, Ranking Member Cole.

Some of the problems that we have when Members just show up at the door is that our staff, unlike those of us who work every day with you or know of you because we work here in D.C., they don't know who is a congressperson and who is not. And we have had several people who have protested or who are angry with the immigration system or any other type of child welfare system that we do.

People do come in and try to impersonate other people to try to get in those doors. We want to make sure the safety of those children is seriously the number-one priority. Letting people just walk into the facility does not protect them if we would have someone who is misrepresenting.

The other piece is that when someone, especially someone who is in Congress, comes to a facility, the staff would want to really be there to answer your questions. That means whoever that staff is that we take off of serving kids is with the congressperson, and we are not—we might lower the number of children that are being cared for. That is not healthy for the kids, and what we want to do is always be responsive to you when you are touring one of our facilities.

And we appreciate the change to a 48-hour, 2 business day change. I think that oversight is absolutely critical.

Mr. COLE. Let me ask both of you this. If the Homeland facility were closed tomorrow, what would you do with the population that is currently being housed and sheltered there?

Mr. HAYES. So, again, Ranking Member Cole, that is just shy of 900. So, you know, we would move them into permanent beds. But again, that would limit some of the permanent capacity that we have immediate access to right now.

And just to note, sir and ma'am, we have not designated any children to Homestead since July 3rd, and we have not designated any children to any of our influx shelters since July 17th.

Mr. COLE. And that was very much my experience with the Obama administration. I remember talking to Secretary Burwell, she said, look, we are trying to get kids out of there as rapidly as we can. For a whole variety of reasons, one of which they are a lot more expensive than if we can move them into what we think are both more appropriate and more cost-effective. I think that same imperative appears to me to be very much at work here.

If we did—well, let me ask you this. We know we have had a lot of challenges here. Were any of the challenges that you faced a few weeks ago because you just were running out of funds? In other words, Congress had not acted on the administration's emergency request for 58 days. Did that make things different or harder?

Mr. HAYES. I think the lack of appropriations definitely created a high level of uncertainty amongst the program. And that does

make it very challenging for us to move in the direction that Assistant Secretary Johnson and I would like—

Mr. COLE. Well, did you have to make reductions because you weren't certain whether or not we would actually pass the legislation and reduce your services to try and stretch out your dollars.

Mr. HAYES. We did that as well, sir. As well as had to scale back certain services in accordance with the Anti-Deficiency Act.

Mr. COLE. I appreciate that very much. My time is about up, Madam Chair. So I yield back.

Ms. DELAURO. Congresswoman Lowey.

The CHAIRWOMAN. Thank you for your testimony.

This committee, as part of the fiscal year 2019 spending bill, included a funding prohibition that prevents DHS from using information collected by HHS to detain, remove, or initiate removal proceedings against the sponsor of an unaccompanied child, and yet the original MOA between HHS and DHS still stands, and many worthy sponsors are still terrified to come forward, leaving children for extended periods of time in shelters across the country. The Federal Government, and in particular the Department of Health and Human Services, should not in any way use vulnerable children as bait.

I went on that trip to Homestead, and this is the issue that haunts me because we did not get the information directly. Director Hayes, aside from information used to determine a sponsor's fitness, such as a criminal record, does HHS currently share information of potential sponsors with the Department of Homeland Security?

Mr. HAYES. Yes, ma'am, we do. At the time of discharge, once a child has been properly run through the sponsorship process. When a child is discharged to a sponsor, we do send—as I notified on the tour, Chairwoman DeLauro—

The CHAIRWOMAN. Excuse me. This is just shocking. I was shocked when I heard it there. Given the funding restriction, why is this happening? And are you aware of DHS using information from HHS to detain or remove a sponsor of an unaccompanied child? Is this arrangement or the perception of such an arrangement creating delays for finding safe placement for these children?

Mr. HAYES. So a couple of questions you ask, ma'am, and I want to answer all of them. First off, to finish answering the prior question, once a child is discharged from our care to go to the family, to the sponsor, as they await their hearing, they are then under the jurisdiction of the Department of Homeland Security in order for them being referred back to the Executive Office for Immigration Review for their court case.

The CHAIRWOMAN. Do you have a responsibility legally? That is not my understanding according to law that HHS must transfer all information to the Department of Homeland Security.

Mr. HAYES. I wouldn't say that it is all information, ma'am. All it is, is where the child is going and who they are going to be with. And so that they can—in order to get—

The CHAIRWOMAN. But who is the sponsor? So if the sponsor is undocumented, you give that information to Homeland Security?

Mr. HAYES. We do not share the immigration status of any of our sponsors.

The CHAIRWOMAN. What information do you give them? It seems to me that you can——

Mr. HAYES. We give them——

The CHAIRWOMAN [continuing]. You are not checking the person's health, whether they are capable of supporting the kids.

Mr. HAYES. We are.

The CHAIRWOMAN. But if they are undocumented, you give that to Homeland Security. So are you surprised that sponsors are not coming forward, that they are afraid to come forward?

Mr. HAYES. Ma'am, I just will add, again, when we discharge a child to a sponsor, they then move under the jurisdiction of the Department of Homeland Security and Department of Justice for their immigration proceedings, and our responsibility ends. We do not share that immigration status, and the immigration status of the sponsors is not a major determining or automatic disqualifying factor for us to discharge a child.

The CHAIRWOMAN. Of course not. But why do you believe that the sponsors are scared to come forward? What do you believe the impact is that fear has on the processing time to place a child with its sponsor? We were talking to some of these kids at Homestead——

Mr. HAYES. Yes, ma'am.

The CHAIRWOMAN [continuing]. And you just don't ask every question. But I wondered, a young man who has been there for 56 days has a father who is working, has a paid job for 7 years. Why is he still there? What other information?

Do you think that——do you have, and then we will have to check on the law. You are saying that you have an obligation to turn this information over to the Department of Homeland Security?

Mr. HAYES. Once we discharge a child, they go under the jurisdiction of the Department of Homeland Security, and we simply share that information as to where they are so that they can be further communicated with as their case goes through the immigration court system.

And I just will add, I have no doubt that there are certain sponsors that are concerned with coming forward. I am sure that that exists. I would acknowledge that to you all today.

However, I think if you look at our discharge rate, specifically over the last 4 to 6 months and how it has improved, I would reject the argument that there is a widespread pattern of sponsors, you know, too scared to come forward. Because we are discharging children as quickly and safely as we can with some of the highest discharge numbers that the program has seen.

The CHAIRWOMAN. It seems to me, and I will conclude my question because my time is almost up. It seems to me that——and I think it was for the first part of our discussion at Homestead, there was no admission that the information was transferred at any time to Homeland Security. And after we kept pursuing and asking those questions, we realized they do.

So it would seem to me we have to look at this law very carefully because if you are going to place these children——and to me, I am not even going to discuss the Homestead facility. But if you are going to place these children in a home with a family, which we all agree is the best place for them——

Mr. HAYES. Absolutely.

The CHAIRWOMAN. For the first part of our visit, we were told that information is not transferred to Homeland Security, and then it was clarified that it is.

Mr. HAYES. If I may, with all due respect, ma'am? I made that comment in the command center, which was after our first brief huddle in the ORR building. That was our very first stop, and I shared that directly with Chairwoman DeLauro—

The CHAIRWOMAN. Let me end here at this point. It looks like we have more work to do in that regard.

Thank you, Madam Chair.

Ms. DELAURO. Mr. Moolenaar.

Mr. MOOLENAAR. Thank you, Madam Chair. And I appreciate the hearing today, and I appreciate your testimony today.

Also just wanted to thank you, Director Hayes. I know you and your staff conduct weekly phone calls with congressional staff to keep us up to date on the status, and I appreciate that, and I know the staff appreciates that as well.

I wanted to talk a little bit about kind of what the lessons we have learned. When there was a surge in 2014, what lessons were learned in that, and how are we applying those lessons today? That is one question for you both.

And then also I want to talk a little bit about how we are recruiting providers. That is something that, you know, how can we get the message out. How can we improve that so that people are getting the best care possible?

So if you would maybe start with kind of the lessons learned from the previous surge and how we are implementing that?

Ms. JOHNSON. Thank you, Congressman.

Lessons learned for me, I started in September, and so things had already reached crisis stage when I arrived. I think the biggest lesson I learned is that this doesn't just happen in this administration. It happened in previous administrations. And it even happened before, but not to this extent.

That the lesson learned should be we should not wait and then respond to surges in a crisis response management system. We need to respond in a—we should be prepared because this continues to happen over administration to administration.

We should be prepared to do it with conservative tax and financial principles so that we are not wasting any dollars, and we should always have these beds available so we are not having to use influx and that we could put kids into loving shelters and move them quickly to their parents. That was my lesson learned.

Mr. HAYES. And I just would add, Congressman, I think one thing that we have learned over the last number of years of this program is that migration patterns are often extremely difficult to predict, and so that is why Assistant Secretary Johnson and Secretary Azar and I are committed to increasing the number of permanent capacity State-licensed beds in our network so that the use of influx beds is exceedingly rare. That is our goal.

One thing that we have specifically done recently, you know, how to look forward, and to how to expand that capacity that we are speaking about and committed to at HHS. Just this last Monday, I had a phone call with our whole grantee network, the leadership

of our grantee network, and I put forward our desire and the goal of where Assistant Secretary Johnson and I want to take this program.

And I told them that they are going to be partners in that endeavor. And so if there are opportunities for them to increase capacity at their current permanent shelters, please let our project officer team know that. If they would like to open up additional permanent licensed shelters, please let us know that, respond to our Funding Opportunity Announcements.

And if there were other grantees and nonprofits and organizations that have the capability to partner with us as from a child welfare perspective that are not necessarily providing a shelter for ORR right now, please bring that to our attention and make sure that they are aware of the Office of Refugee Resettlement's needs in the coming weeks and months as we move forward with additional Funding Opportunity Announcements.

Mr. MOOLENAAR. And are there barriers that you are finding towards increasing the capacity?

Mr. HAYES. There are, sir. At the end of the day, the final say on granting of a license and occupancy to a State-licensed permanent shelter, even one that we fund and pay for as the Federal Government through HHS, lies with both local officials and the State officials through a licensing perspective, occupancy from the local fire marshal and the local licensing board.

And you know, we are—honestly, sir, we are experiencing challenges, I would say, from both sides of the aisle. Some Governors don't want, you know, illegal immigrants in their States. I think there is an understanding that they might take some of the resources away from the State, that HHS cares for each and every one of the needs there.

And then also some from the left that don't want children detained or locked up even in a 100-bed permanent licensed shelter. So those are some challenges that we are definitely facing, sir.

Mr. MOOLENAAR. And I know you mentioned "quickly and safely" released to suitable sponsors. And I think that is something those two, quickly and safely, that those don't always work hand-in-hand. You want to make sure there is in some way verification, in some way accountability for whatever sponsors. Can you speak to that just for a moment?

Ms. JOHNSON. We do thorough background checks, and we have been operating this program for a very, very long time. So we do the background checks. We do home visits. We gather information about the sponsor. And so we really worked hard to make sure that this child is going to a safe home. And we do this—we have got this down, and we do it as quickly as we can.

Mr. HAYES. And I would just add, sir, in closing that the final say on the discharge of that child does fall to Federal oversight staff, our Federal field specialist team and our Federal field specialist supervisors. As they kind of look through the entire case of that particular child and the sponsorship care package and reunification package, again to make sure that all the policies and procedures were followed and that that is, indeed, the safest and best path for that child to go into.

Mr. MOOLENAAR. Thank you. And thank you, Madam Chair.

Ms. DELAURO. Congresswoman Watson Coleman.

Mrs. WATSON COLEMAN. Thank you, Madam Chair, and thank you to the—thank you and thank you to the ranking member for this hearing.

Thank you for being here.

We did have a very thorough visit, I think, at Homestead, and I am grateful for that. I do think, however, it is important that Members of Congress who have identification can come to these facilities without first being—getting permission to come in so that we can actually see what really happens on a day-to-day basis.

I got a number of questions. Number one is the educational offering that we saw at Homestead was really very disturbing. The facility, in and of itself, was very counterintuitive to learning. It was loud. It was noisy. You really couldn't hear yourself think, let alone—you couldn't hear what people were saying, let alone thinking. So I really think that that is a particular challenge just being in those classrooms and expecting those children to learn.

What happens if a child doesn't speak English or Spanish? How does that child get to interact and be taught? Are there other languages being taught, being spoken at Homestead, Mr. Hayes? Thank you.

Mr. HAYES. Yes, ma'am. We do have translators available. And I will just note that we do have a significant number of children that come into our care that are not Spanish speaking. We have a grantee in the Chicago area that has 38—the ability for their staff to speak 38 different languages, and when our intake team determines that or if a child were to arrive at another shelter after, we will absolutely transfer that child to a facility where we can communicate with them just as quickly as we can.

Mrs. WATSON COLEMAN. Thank you.

I know that the Homestead facility is an influx facility, and so children don't necessarily stay there and shouldn't stay there very long. But you have educational standards and you have a curriculum, and none of it is curriculum or standards that have been decided by the State of Florida as appropriate for the educational offering.

And my question is why do you not use their standards and their curricula?

Ms. JOHNSON. Thank you.

It is really critical to remember that the child that comes over the border, sometimes they have never been in a classroom in their lives. And sometimes they have been in 1, 2, or maybe 3 years of—

Mrs. WATSON COLEMAN. Yes, I agree with that. But I don't understand why you think that this for-profit company is more capable of developing curriculum standards for these children than those people who are sanctioned and educated and certified by the State of Florida.

Ms. JOHNSON. The public school system's standards and curriculum do not adapt to the situation that we have with the children who have had no learning, and we want that child—it is only 30 days—to have the type of learning so they can leave the facility and be successful wherever they go.

Mrs. WATSON COLEMAN. I think that is very—

Ms. JOHNSON. And that does not fit——

Mrs. WATSON COLEMAN. Okay, thank you. I think that is a very interesting concept.

Why is it that there are only five certified teachers at Homestead?

Ms. JOHNSON. Thank you.

The teachers that we are able to recruit, we again look for the Spanish speakers, those that have some social work background, ability to do counseling and understand the journey, the trauma-informed care. So we look for teachers who can do a 30-day learning experience that, in addition to being a teacher—and we do have some that are certified—we can move forward.

The other piece with that is that many of the teachers are not looking for an influx type of employment where in 30 days, they might not have employment. Teachers may—they like the long term.

Mrs. WATSON COLEMAN. Okay. Thank you.

You mentioned that when there was a threat that you wouldn't have sufficient resources, that you had to scale back on certain services. Could you just list for me quickly some of those services that you scaled back on?

Mr. HAYES. Yes, ma'am. They would have been education, recreation, and legal services.

Mrs. WATSON COLEMAN. So that leaves feeding and sleeping and bathing perhaps. If you do not accept any more children into Homestead and Homestead then becomes vacant, what is our financial obligation to this facility when there are no children there?

Mr. HAYES. It is on a contract, ma'am, and that is something that we are working very closely with our team on. We could modify that contract, and that is an ongoing operational decision that we are having at the Office of Refugee Resettlement.

And I will just promise to you and give you my word now. I would agree, ma'am, that the education building that we went into, that the noise level was something that was a bit of a problem——

Mrs. WATSON COLEMAN. Yes, okay.

Mr. HAYES [continuing]. In some of the curriculum. And I will work with my team on looking——

Mrs. WATSON COLEMAN. Mr. Hayes, thank you. You know, I am really concerned about what our financial obligation would be to a vacant facility. And so I don't need to know what you could do. I need to know what you will do and what you legally can do in that situation. And if you are not prepared to answer that right now, we can through the chair accept that explanation.

Mr. HAYES. As soon as we make a decision, ma'am, I will be sure that Congress finds out through the Assistant Secretary for Financial Resources and her staff.

Ms. DELAURO. Because Tornillo was shut down. There was a contract. What was the amount, and what happened at the end of that?

Mr. Harris.

Mr. HARRIS. Thank you very much, Madam Chair. And thank you, Assistant Secretary and Director, for being here today.

First of all, you have got to realize, of course, it is not your fault. This is Congress' fault. I mean, the bottom line is this is a failure of Congress.

First, we refused to deal with the policies that incentivize UACs crossing the border, and then we refuse to fund you adequately. I mean, the bottom line is I think it should be noted that when President Obama requested emergency funds during his administration, it took 25 days to get those funds to you, and this time, it took 58 days to get the funds to you.

Now I am going to ask you, the bottom line is so when the Republicans controlled it, we actually got funds promptly to take care of the children. When the Democrats controlled it, they whistled past the graveyard for a while.

In those additional 33 days that it took us—and by the way, our 25 days was up, oh, that is right, in the middle of the Memorial Day recess while we decided to go home instead of taking care of the children issues at Homestead. Could you have done something with funds, had those funds been released almost a month earlier in terms of speeding the—what has occurred since the funds were released, which is speeding the discharge of these individuals from Homestead to other facilities or places?

Could you have done a better job if we—if Congress didn't whistle past a graveyard through its Memorial Day recess and not provide the funds?

Mr. HAYES. Dr. Harris, we will always be able to do a better job with the—

Mr. HARRIS. Sure. Of course, you can. This is crazy. This is a failure of Congress.

Now HHS is not a law enforcement tool, but it certainly should cooperate with law enforcement, shouldn't it? I mean, we shouldn't put a wall between Federal agencies in terms of enforcing the law.

And what I am getting at is, you know, human trafficking is a huge issue, and we know that some of these unaccompanied children are trafficked not only for human trafficking into prostitution, but into gangs. And what I see here is most of these children come from the Northern Triangle countries. That is where MS-13—that is the base for MS-13. MS-13, a huge issue in Maryland.

I would hope that we don't build a firewall between agencies that would prevent the investigation of potential gang trafficking and human trafficking into this country. Now look, I am going to apologize that, you know, for the accusation that somehow you are child abusers. Because child abuse is actually a crime.

I am going to ask you, by the way, is the Homestead facility subject to Florida State law?

Ms. JOHNSON. No.

Mr. HARRIS. So if a murder is committed, it is not subject to Florida State law in the Homestead facility.

Mr. HAYES. No, our facilities are subject to all Federal and applicable State laws, yes.

Mr. HARRIS. Of course, it is. And of course, you do realize that child abuse is a criminal act under Florida law?

Mr. HAYES. Yes, sir. And the Florida Department of Children and Families would investigate.

Mr. HARRIS. Correct. And that your—for instance, your physicians and social workers are bound under law to report child abuse.

Mr. HAYES. Yes, sir. As well as ORR policies and procedure.

Mr. HARRIS. Correct. In the past let us say 2 months, how many reports have been made by your licensed physicians and social workers under Florida law that child abuse has occurred in the facility?

Mr. HAYES. I don't have that exact number, sir. But I would be happy to get it back to you.

Mr. HARRIS. Is it a handful? I mean, because this is under Florida law because, again, the allegations—and look, in another room here, there are other baseless allegations being made against the Trump administration and its officials. The bottom line is that you were accused of child abuse, which is a criminal act. And I want to apologize for that because there is no basis for it. And I believe when you get me that number, you are going to realize that there is no basis for systematic child abuse occurring at this facility any more than systematic child abuse occurs at a public school or other institution.

Now let us talk about a little bit about what we can do going forward. Because this is in the past, we got you the monies you need. The bottom line, and I want to bring up the question because it has been said that we have to—if we close this facility, how do unaccompanied children flow from the border to a sponsor? How would that occur?

Mr. HAYES. So the process, sir, once a child comes into our care and custody after being referred by DHS, we immediately after processing them at the facility, again providing them initially a hot shower, a warm meal, and the initial medical exam. We immediately begin the sponsorship reunification process to identify a sponsor, run the appropriate background checks on that sponsor, and then discharge the child just as quickly as possible.

Mr. HARRIS. Right. But if Homestead doesn't exist, where would that child go?

Ms. JOHNSON. Our plan is that they would go to a permanent licensed shelter so that they don't have to go to influx facilities. But at this time and with the numbers coming over the border, we have needed the influx. But they are dropping now. We are watching the trends. We are watching the trends from last year and the year before to find out is September going to be high again? Is November?

So we don't want to change anything drastically until we know that the new normal is.

Mr. HARRIS. I get it. Thank you very much.

Thank you, Madam Chairman.

Ms. DELAURO. I just might add that the bulk of the money in the supplemental is for permanent licensed beds, understanding your need. And that is what we did, so that we could close the influx shelters down.

With that, Congressman Pocan.

Mr. POCAN. Thank you, Madam Chair.

And I just want to say Representative DeLauro's opening comments reflect exactly how I feel from the visit and being there. I think the thing that I took away was I would love to figure out how

we would never have a facility like this again, period, given the conditions on multiple levels.

I mean, they are not the horrific conditions of the no soap and toothbrushes. But for \$750-plus a day, those are not conditions that are acceptable.

I want to ask, so it looks like 1,400 children—because you are now down to 890-something—in a matter of a few weeks have suddenly been moved from there. I think the question that we asked that day and hopefully have the answer now because it is 9 days later, how many of them were placed in homes, and how many just are transferred to other facilities?

Mr. HAYES. So I actually did have the answer that day, sir. We provided it to Chairwoman DeLauro and her staff.

Mr. POCAN. Okay. You can go ahead and say it.

Mr. HAYES. Looking specifically at those numbers of that day as 900 that had been discharged in the 12 days you all were referencing. About 810 were discharged to sponsors, you know, family, close friends, and about 90 were transferred, either due to the fact that there is no identified sponsor in the country or they had medical issues.

Mr. POCAN. Sure. So I guess the question really is why all of a sudden in a few weeks could you move that when for so long those facilities are holding people at \$750 a day? And let me just say that conditions, the education. I don't think any of you think that that really is education that is happening there for that \$750.

I taped the background sounds while we were there, and you probably can't hear it there. It was a constant—let me turn my volume up.

[Playing audio.]

Mr. POCAN. I couldn't hear the person with a microphone that was about 8 feet away trying to—in a classroom because of the background noise. There is no way that you are having education occur with this kind of background noise.

The fact that mental health professionals, anyone who has come leaving trauma in a country, violence is why they left in the first place, went through a treacherous journey to get there, and then being separated from their families, and then the mental health in some cases is a Skype session with a mental health professional in Texas?

I guess what I am getting at is people back home in Wisconsin say how can this possibly cost more than the Four Seasons or the Trump hotel, and yet the conditions are, you know, bunk beds stacked in rooms, no education whatsoever, no real mental health whatsoever. How does it get to be \$750 a day?

And at first you said, well, initially there is an expense. This facility has been around, as we have pointed out, for a long time. So there is no initial expenses we are still paying for. How is it that we are not getting ripped off?

And then the second part to this is I talked to 4 girls—one who had been there 75 days, two were there 60, one 45. The one girl that was there for 60 days just the previous week, they reached out to her brother who lives in the United States. That means for 53 days, they didn't try to connect that person to a family member at \$750 a day.

What I am getting at is this is a very profitable venture with very little incentive to transfer people. But all of a sudden in a couple weeks, you transferred 1,400 people. So some fire got put under the system.

But that is screwed up. And by every smell test that people in Wisconsin live by, that doesn't make any sense. Can you address the costs and specifically that issue of like people sitting there for 53 days before they are finally trying to be connected to a family member?

Mr. HAYES. Yes. So, again, I can't speak specific to examples. So I don't know if there, you know, maybe that is when she shared that she actually had a brother. We have seen that before when children come into our care in custody, sir, and they don't—

Mr. POCAN. Okay. How much does it cost? Because I want to get one other question, and I got a minute and 9 seconds.

Mr. HAYES. Right. So the approximate cost at Homestead is approximately between \$700 and \$750 a day, sir.

Mr. POCAN. How is that justifiable? I mean, given bunk beds, not really educational opportunities, not really teachers, Skype sessions with mental health.

Mr. HAYES. Influx shelters historically have cost more, and I think it is important to note, Congressman, that when that contract was originally awarded, two for-profit companies put a bid for it and three nonprofits, and it was awarded in an open and fair competition. It is not costing the Federal Government additional money because it is for-profit.

Influx facilities—

Mr. POCAN. Okay, if I can just pause this because I do want to go to another question. So it is still three times more than the other shelters. I still think there is a real cost issue that is totally indefensible, and we need to address that, which is part of why these facilities should go down.

The question I wanted to get in my final seconds is we—and Mrs. Lowey asked this question as well. On the—I am just trying to find where this is now here. Well, actually, I am not going to have time for this. I will leave it at this.

But I do have more questions. We gave you a list of 107 questions. Did we get the answers on those returned to us?

Ms. DELAURO. No. The answer is no. We worked on it, but we don't have the answers.

Mr. POCAN. If I could, just 20 seconds, please, on this? This is the question I was trying to get out is the information, you said that they fingerprint everyone and that information is given to Homeland Security. All the calls are given to Homeland Security. And the question we had—that is what you told us that day.

Because a question I had, you said you would get back to us on, was what do they do with the information they get? And you said you don't know, which I didn't expect you to then. But 9 days later, do we know if they use that information in any other way?

Mr. HAYES. I would refer you to the Department of Justice as to what they might do with the fingerprint results that we share with them. But—

Mr. POCAN. I did ask you that question that day, and you said you would get back to me at the end of the trip, which you didn't.

So now it has been 9 days later. Seriously, do you not know what they do with that information?

Mr. HAYES. I believe, sir, we just have to agree to disagree. I said that I would refer you to Department of Justice and my colleagues on that specific thing. Our—

Mr. POCAN. Aren't you at all inquisitive, being in your role, to what they do with that information? Like wouldn't that be curiosity that if I give this information and they use it in a detrimental way, that is why it is going to be harder to find some of the placements?

I mean, I think that is a very fair question. I asked you 9 days ago.

Mr. HAYES. I think that is a fair question. I would also answer one of your questions, sir, that we are not fingerprinting moms and dads at this moment, nor are we fingerprinting grandparents and adult siblings, provided there is no red hits on the biographic background check. And I did make that crystal clear that day.

So we are not fingerprinting every single sponsor. I just want to clarify that.

Mr. POCAN. Right. But you still don't have—that is fine. I will take it to the other Department.

Ms. DELAURO. The non-fingerprinting is what is allowed. That could have been implemented many, many months before, keeping in mind that Homestead has been open for a year and a half. And only in the last few weeks have we seen the movement of children.

With that, Congresswoman Roybal-Allard.

Mr. HAYES. Yes, ma'am. Due to the fourth operational directive that we put forward. Yes, ma'am.

Ms. DELAURO. And I will just say I have got the yield time.

Ms. ROYBAL-ALLARD. Ms. Johnson, I want to talk a little bit more about Homestead because in your written testimony, you state that ORR care provider facilities are not prisons. Now I believe that, based on my visits to licensed ORR facilities, that that is true. But yet I have to tell you that throughout our visit to the Homestead facility, it was obvious to all of us that the shelter was run more like a prison than like a child-appropriate housing.

And I understand the importance of supervision of these children to ensure their safety, but these children are living in overly restrictive conditions. For example, in addition to the teacher, when we go into the classroom, there were four other employees stationed in each corner of the classroom, watching these children.

And in other ORR facilities that have I attended which are non-influx, the children are in classrooms. They have one teacher, and they move much more freely and independently in that facility.

We have heard from child welfare specialists time and time again that this kind of restrictive setting like Homestead is extremely harmful to the children. And the chairwoman outlined other areas where there is this lack of privacy. We saw the children having to walk in the straight line, monitoring as they were moving from one room to another.

My question is what of our policies stipulate the adult-to-child ratio in these influx facilities, which appear to be different than in your other facilities? And while ensuring the safety of these children, how can this policy be modified to provide a less-oppressive environment, as well as much-needed privacy, as you have in your

licensed facilities? What is the difference? Why is it so—either one of you.

Mr. HAYES. If I may, Congresswoman?

Ms. ROYBAL-ALLARD. Either one.

Mr. HAYES. So the youth care worker ratio is the same at both Homestead and at Boys Town, and I know a couple of your committee staff went with us to Boys Town after the Homestead tour last week. And there, we had the youth care workers also sitting in the classroom with the teachers. So there is not a difference, ma'am.

Ms. ROYBAL-ALLARD. But my question is that—but there is a difference in your ORR licensed facilities. You don't have five people in a classroom.

Mr. HAYES. No, I just described—we have the appropriate number of youth care workers supervising both the children and the teachers. You would have seen both youth care workers that you saw in the four corners you referenced in Homestead. We also have those at Boys Town and—

Ms. ROYBAL-ALLARD. I guess my question is when I have visited your State-licensed ORR facilities, gone into a classroom, there is a teacher there. The kids, you know, are learning. But in Homestead, there was actually—if you counted the teacher, there were five adults looking, watching these children. And my question is why is it necessary at these influx facilities to have that kind of surveillance of children 24 hours, where it is not done in your regular licensed ORR facilities?

Mr. HAYES. What I am saying, ma'am, and I would want to know exactly what shelter you went to where that was not happening. Because, again, we immediately went to Boys Town, which is a licensed shelter 30 minutes from Homestead, and that is what is happening.

I will say this. If there are thoughts or, you know, some direction that the members of this panel would like us to consider, I am more than happy to take those back and have discussions with our child welfare experts at ACF and ORR. But a 1-to-8 child ratio for youth care workers and 1-to-12 for case manager—I am sorry, 1-to-8 for case managers and 1-to-12 for clinicians are standard child welfare—standards in the child welfare system.

Ms. ROYBAL-ALLARD. In classrooms? And they have to walk in these straight lines? I mean, they can't move freely.

Mr. HAYES. There is structure at each of our shelters, ma'am.

Ms. ROYBAL-ALLARD. I think we need to look at that, and I think we need to work together to find a better way. Because as I said earlier, child experts are telling us that this is not healthy emotionally, mentally for these children to be treated in this way. So let us work with the subcommittee to try and—

Mr. HAYES. You have my commitment. I would love to do that. And again, the majority of our staff, both at our shelters and at ORR headquarters, our child welfare experts and social service workers, we share that commitment. Happy to work with you and the committee, ma'am.

Ms. ROYBAL-ALLARD. Okay. And I do have another question, but it would take much longer than my 5 minutes. So I will wait.

Ms. DELAURO. Thank you. Congresswoman Lee.

Ms. LEE. Thank you very much. Thank you, Madam Chair and our ranking member.

And thank you for being here.

First of all, I want to follow up on what Congresswoman Roybal-Allard was talking about in terms of the structure. You say they are not jails or prison. I say you are warehousing children. It feels like a prison, okay? The structure and the organization of Homestead feels like a prison.

Now given that it feels like one to myself, I am a clinical social worker by profession, I know what it must feel like to the children. And so in a case management plan, how do you address that in terms of a child going through this system in a warehousing prison-like setting?

First of all, the trauma, 100 percent of these children have trauma, and I know we were told that they are assessed for that. But you can assume and you know 100 percent have trauma, and so 100 percent need clinical trauma-informed care.

How do you—they are not all receiving that trauma-informed care. They are getting maybe counseling, maybe not, maybe a week video session, maybe not. And then, as you move through whatever case management plan that you have, how do you deinstitutionalize these children as they move forward and move on to their sponsors?

Because I know for a fact that when young people get out of jail, you have to have a transition period so that they can become—so the deinstitutionalization process works. So how do you do that in the case management plan?

Ms. JOHNSON. Thank you, Congresswoman.

And as you know as a clinical licensed social worker, the length of time in an influx facility is critical, which is why we are working to reduce that length of time that they are there. More critical is that we don't want them sitting in a Border Patrol station because of that very trauma.

As probably when I got my social work degree, that what we have learned about neuroscience, ACEs, trauma has changed considerably in the last 10 years. We are hoping and training our staff to deal with those issues.

The deinstitutionalization is in addition to dealing with the trauma from the journey from home country and, you are absolutely right, from sitting at a border and being in an influx facility with all of the other children. We do know, though, that those supports are very critical.

One very important piece. If someone is assessed with serious trauma, serious mental health issues, they are not placed in our influx facilities. They are placed in our licensed permanent shelters that are specialties for just that.

Ms. LEE. Well, you can't tell me 100 percent of these children don't have trauma-related mental health issues.

Ms. JOHNSON. No, I would say that many of those children have trauma-related—

Ms. LEE. One hundred percent do.

Ms. JOHNSON. But very serious mental health issues are moved elsewhere.

Ms. LEE. Yes. But you don't have mental health professionals that have an expertise in trauma-related psychotherapy to help 100 percent of these children.

Ms. JOHNSON. No. But they do have the training in trauma-informed care. As you heard me say in my testimony, everybody is trained—

Ms. LEE. But you don't have psychiatrists, psychologists, clinical social workers to administer the trauma-informed therapy for 100 percent of the kids.

Ms. JOHNSON. We do have access to all those mental health requirements.

Ms. LEE. But not all of the children receive that?

Ms. JOHNSON. Not every day.

Ms. LEE. Okay. Now secondly, let me just ask you about this contract. Well, first, Director Hayes, you said something that was very interesting, and I would just like for you to respond. You said some from the left don't want children, kids locked up. What did you mean by that?

Mr. HAYES. What I—

Ms. LEE. Some from the left don't want children locked up?

Mr. HAYES. What I am saying is we have—

Ms. LEE. What did you mean "some from the left" don't want children locked up?

Mr. HAYES. What I was commenting is that we have received challenges from both sides of the political spectrum in the history of this program.

Ms. LEE. From the right and the left?

Mr. HAYES. That is what I am saying, yes, ma'am.

Ms. LEE. That is a strange way to present testimony to this committee, but if that is how you present it, some from the left don't want children locked up, okay. I know children—I know individuals who are not from the left who don't want children locked up.

Mr. HAYES. What I was saying, ma'am, is that they don't want any of our shelters, even our State-licensed shelters—

Ms. LEE. I understand. But I know people who are not from the left who don't want children locked up.

Let me ask you a little bit about the contract since we don't have it. I want to understand. It is a no-bid contract. What is the profit margin? The daily rate is \$750 per child. That is, what, about a \$1,000,000, depending on how many children are there, a day. What is the profit margin? What is the G&A rate on that, the general and administrative cost rate?

Mr. HAYES. I don't have the specific information on that, ma'am, but will be happy to get back to you with that.

Ms. LEE. Well, let me ask you then is there an incentive to make sure that these children are processed expeditiously or a disincentive to keep them there so the contractor can make more money?

Mr. HAYES. The answer is no to both of those, ma'am. It is not our desire to keep kids longer than absolutely necessary, nor do I ever want to put any of our grantees or any of our ORR staff in a position where they are simply discharging kids for the sake of discharging them.

Ms. LEE. Well, are there penalties if the contractor doesn't perform based on the contract requirements, which, again, we haven't

seen. So we don't even know what the contract requirements are in terms of the children.

Mr. HAYES. Right. It is not tied to length of care or discharge rate, I can tell you.

Ms. LEE. What is it tied to?

Mr. HAYES. I would have to get you some more information on the specifics of that contract, ma'am.

Ms. LEE. Listen, I was a Federal contractor, and I know what these no-bid contracts are like. I know how you add on. Of course, I couldn't add on.

But how is this contract performed, and when does it end? And do you intend to—you didn't answer the chair's question about when the contract is going to end and when we are going to shut this down. So do you intend to add on to their contract after November?

Mr. HAYES. Well, okay. So, yes, so November 30th is when the current contract does end. Again, when it was originally awarded, it was not a no-bid contract. There were five folks that went into open competition for it.

And at this point, we are evaluating the needs for our beds and the ability to take kids as quick as possible. Again, my commitment is that we want to reduce the capacity at Homestead down to zero just as quick as we safely can, and we would only utilize any influx shelter in the event that there were no permanent beds to place the kids in.

Ms. LEE. And no plans to get the contractor licensed, and you don't know whether—and can they add on or not? And thank you—can they add on to the contract?

Mr. HAYES. Those discussions are ongoing, and potentially, looking at licensing any of our facilities that aren't licensed is something that we are open to consider, ma'am.

Ms. LEE. Open to consider, but not required by the contract.

Mr. HAYES. Well, again, it is not totally up to us at HHS.

Ms. DELAURO. Congresswoman Bustos.

Mrs. BUSTOS. I want to thank Chairwoman DeLauro for having this hearing today and thank you to the Assistant Secretary Johnson and Director Hayes.

I am going to continue some of the line of questioning that Congresswoman Watson Coleman started regarding the education. So just along those lines, most of us sitting up here are mothers or I know, Mark, you don't have any children—or grandmothers. And so, like, I know that each of us, when we think about the children, we just think about how scared they must be, how worried they must be about what is going to happen to them going forth, all of the uncertainty that is in their lives.

And part of me is thinking that education has to be like the one respite from all of these worries. And as I was preparing for this hearing today, I just was really surprised at why the curriculum isn't something that would fall in line with the State of Florida that has deep experience in educating children. And I know you said that this is—the children are different.

Why the teachers aren't—don't fall under the same level of regulation that public school teachers would. And so I guess, again, some follow-up questions to what Congresswoman Watson Coleman

asked. So does HHS or the Department of Education review student curriculum at Homestead? Can you talk through how that works and like what is being taught to these children?

Mr. HAYES. So the Department of Education is not involved particularly at Homestead, but I know that our staff does work very closely with the staff at Homestead and CHS that runs this particular shelter. And again, I just want to recommit to you that I did with Mrs. Watson Coleman that, you know, this is something that I would agree that is an area for improvement from both the actual facility itself, and it is something that, again, if there are ideas and thoughts and suggestions you have, we are definitely open to considering those in regards to beefing up the education of these very vulnerable children.

We do acknowledge that they are vulnerable, that they are scared. I think that is exactly why Congress, back in 2002, moved the Unaccompanied Children Program from INS at Department of Justice to HHS, specifically inside the Administration for Children and Families. So we share that commitment to taking care of some very scared and very vulnerable children who do have a lot of uncertainty around them.

Mrs. BUSTOS. Do you have anything to add to that?

Ms. JOHNSON. I have toured several of our shelters and also the influx facilities, and at one of the facilities, I watched through when they were in their classrooms and they were learning about homophones. And I couldn't tell you what that is until after I left. I was like I am not sure for a child who is only going to be here 20 to 30 days, that that would be the priority that I would have on learning.

And so we had the conversation about what else gets that child ready to move into the interior and live with their sponsors, back with their parents, especially when they had not had any education in the past. These kids were excited. They were answering questions.

And in most of the classrooms I have gone to, actually, all of the classrooms I have been to, the children were excited about learning. I want to share—I do want to comment on one thing. I am also a mother, and my heart goes out to every one of these kids, but the excitement and the glint in their eye because they know what is coming next and they are getting what they believe is their dream is really, really exciting. And it is a good thing that by law, I am not allowed to take every one of them home because these are fantastic kids. And they get excited to talk English, and they say to me, please, Miss Lynn, talk to me in English. And I will say, talk to me in Spanish so I can learn, too, and these kids are excited.

So from a mom, my heart goes out to every one of those kids. I wish I could hug them all up, but I am exactly where you are. We want the very best, and I always, in my previous jobs and today, I always think this is what I would do for my children if they were in the same situation. So whoever brought that up I really appreciate that.

Mrs. BUSTOS. Okay. I am going to, because we have less than 1 minute left. I am also thinking about, again, how scared the kids must be. We are in hurricane season in that region of our country,

and I know part of getting the kids out of the influx center quickly is because we are in the middle of hurricane season. Do you have an evacuation plan? If something is going to hit, can you talk through what happens?

Mr. HAYES. Absolutely, and as a Floridian myself, ma'am, that is something that I am very sensitive to. But not just hurricanes, but any and all emergencies that might exist where we need to potentially evacuate a shelter, whether it is flooding in Houston or hurricanes in Miami.

The answer is, yes, we do have a plan. It has actually been implemented before and executed at Homestead. Back in 2016 we had to evacuate it. It is done. You may not be aware that we have a planning and logistics team made up of emergency management professionals that serve inside the Office of the Director at the Office of Refugee Resettlement. This plan was made in coordination with the Miami-Dade emergency management folks. In fact, just last week my director of planning and logistics met with the team down there. It is in close coordination also with FEMA and with the assistant secretary for preparedness and response at HHS.

And, again, whether it is a hurricane in Miami or flooding in Houston, we have the ability to move the kids around in order to get them in a safe environment. And, again, as we move into the heart of hurricane season, as a Floridian, the size of the census at Homestead was something that we were very much tracking, and we are always going to make sure that we have plans in place and the very best efforts that we make are to ensure the safety of the children.

Mrs. BUSTOS. I am over my time.

Mr. HAYES. And if I might just add, we actually circulated that plan earlier this morning to several members of Congress. If you would like to get it, we would be happy to send it to you.

Mrs. BUSTOS. I would. I know I would like to see it. I think actually we would probably all like to take a look at that.

Mr. HAYES. Absolutely.

Ms. DELAURO. Yes, and that was requested by Congresswoman Wasserman Schultz. We were told at the time we couldn't get it, you would set up a briefing. But I am pleased to know that we can get it and it can be shared with every member.

Mr. HAYES. And Ms. Mucarsel-Powell as well.

Ms. DELAURO. Ms. Mucarsel-Powell as well, that is right.

Mrs. BUSTOS. I yield back. Thank you.

Ms. DELAURO. Just a quick point before Congresswoman Clark. The ages of these children are 13 to 17. I am trying to think of my grandkids. It is like the 8th grade through the 12th grade, somewhere in there. And as far as we can discern in terms of the education process, that these were kids not tested to know at what grade level they go in or what is appropriate, and I can't have you answer. I can do that in the second round. You can't answer me because I won't take your time. But, Congresswoman Clark, go ahead.

Ms. CLARK. Thank you, Chairwoman DeLauro, and thank you. Nice to see you again, Mr. Hayes. You told Dr. Harris that Homestead is subject to State law, not licensing, but State law. Is that correct?

Mr. HAYES. Yes, ma'am. Federal and State law does apply to the employees and the staff, and we work very closely with the Miami-Dade Police Department in FPS.

Ms. CLARK. So if a child reports sexual abuse, that would be investigated by Florida.

Mr. HAYES. That is correct.

Ms. CLARK. And so there have been, according to your numbers, 412 allegations of sexual abuse. Twelve percent of those, a little under 12 percent, involve staff on minors. So I have a couple questions. The Miami Herald says that the State of Florida has not been permitted to enter Homestead to investigate all the allegations of sexual abuse. Is that your understanding? Can you explain that?

Mr. HAYES. That is not my understanding, and the Department of Children and Families in the State of Florida has been involved in investigations down there. So to the best of my knowledge, they have access to and they are involved in that process when appropriate.

Ms. CLARK. Could you make a commitment to looking into those allegations?

Mr. HAYES. Absolutely, Congresswoman. You have my commitment to do that.

Ms. CLARK. Okay. Are the staff who were involved in these allegations, are they still there? I know this is not ORR staff, but are the staff at Homestead still there?

Mr. HAYES. So in the last 4 years, there have been four accusations that involved staff on UAC. Two of those were determined to be unsubstantiated, one of those was closed administratively by the State of Florida, and the other one, and this actually happened in the last Administration, that person was found guilty and they are currently in jail.

Ms. CLARK. So I am looking at your numbers that said——

Mr. HAYES. I am specifically just speaking to Homestead, by the way.

Ms. CLARK. Okay. So the 412 allegations are broader than just Homestead.

Mr. HAYES. I am not exactly sure what reports or what numbers you are looking at, but I know that there is some additional information that is forthcoming to Congress later this month or early August that will address more of these issues in regards to sexual abuse. I don't know if you want to add anything, Madam Assistant Secretary?

Ms. JOHNSON. Yes, we are going to be providing all the details and information on assaults and the questions about those. One of the key things——

Ms. CLARK. What is the timing of providing that information?

Mr. HAYES. I think, again, I would say late July or early August is my understanding, and if that is different from that, I promise you we will get back to your staff.

Ms. CLARK. So next week? In the next 2 weeks?

Mr. HAYES. That is my understanding, and if that changes, I promise you we will let you guys know that just as quick as possible, ma'am.

Ms. CLARK. Can you let me know, I was there. I was able to see this telephone that is preprogrammed so kids can report, but it is a rather open cubicle next to a ping-pong table. Does that comply with their own regulations on reporting and privacy?

Mr. HAYES. Yes ma'am, it does, and, again, I was there with you and I pointed the phone out. And you are right, it is preprogrammed to report any type of abuse as well as give the children access back to home consular officers.

Ms. CLARK. Okay. And you feel that is compliant with privacy regulations.

Mr. HAYES. I do, but again, if you have suggestions on improving that or modification on that, I would be happy to discuss that with my team.

Ms. CLARK. Okay. I want to go back to a question that Chairwoman Lowey asked you about your legal obligations to share information with sponsors on DHS. I appreciate Assistant Secretary Johnson's comments on children may be excited about their futures, but it was pretty startling to have it confirmed by staff when I was at Homestead, the children who turn 18 while they are there, that information is given to DHS 2 weeks before their birthday, and then they are shackled and removed from the property. That was confirmed by staff when we were there. I am sure you would also be able to confirm that, Mr. Hayes. Are you legally obligated to share the information on sponsors with DHS?

Mr. HAYES. It is my understanding that we are required to through a statement of principles from the very early onset of the formation the Department Homeland Security, because when children are discharged from our care, our statutory authority ends, and then they fall under the jurisdiction of DHS.

Ms. CLARK. What about on sponsors? I know you are no longer fingerprinting family members, but what about that information on sponsors? Are you legally obligated to share that with Department of Homeland Security?

Mr. HAYES. It is my understanding that we are not legally obligated, ma'am.

Ms. CLARK. So then why do you do that?

Mr. HAYES. We do not share fingerprints with the Department of Homeland Security.

Ms. CLARK. But you did everything until very recently, right, or no?

Mr. HAYES. We quit in December with adult household members.

Ms. CLARK. Why was it done before December?

Mr. HAYES. I think you are referencing the memorandum of agreement which, again, was put into place before my time at ORR, so I can't really speculate on all that went into the decisions behind that.

Ms. CLARK. So there was no legal obligation, but that was the flow of information. And I think as we talked about when we were there at Homestead that maybe 2 weeks is not the time that we should be focusing on these children turning 18. Have you made any improvements in that time period?

Mr. HAYES. So personally, ma'am, again, I was with you on that tour, and I thought that was an excellent idea, and the team is working towards that. But as I said that day, you know, if it was

up to the grantee staff and the ORR staff, we would let these kids stay with us until they are 19, 20, 21, if that is what it meant. But, again, HHS' statutory authority over those children ends on their 18th birthday. And because most of the children are referred to us by DHS, they already know their age, ma'am, and they know where, you know, we designate them to because they bring them to us at our respective shelters.

So, you know, again, when they turn 18, they are no longer children, and so they then go into the custody of Department of Homeland Security.

Ms. CLARK. In shackles. My time has expired.

Mr. HAYES. Any questions to that, I would refer to my colleagues at DHS.

Ms. DELAURO. So much of this revolves around rescinding the MOA, which we will keep repeating, and it should be terminated, rescinded, and gone to protect the children and to protect their families. To both of you, you have said that the ORR wants a network of 20,000 State-licensed. But at its capacity, ORR had 15,000 children in care, and the main reason you had so many children in care was because of the excessively long stays in care. Let us repeat that: 35 days in the Obama Administration. Directives which you now have turned around, to your credit, but there were directives that were put in place which made these excessively long stays in care, and that was because of the MOA. The fingerprinting requirements, and the data sharing with DHS ground this process to a halt, created chaos at the border and children in inhumane conditions, when all the time we had the ability to move these children. My question: what justification do you have for needing long-term capacity of 20,000 permanent beds? Are you basing this on any CBP projection data?

Ms. JOHNSON. Thank you, Madam Chair. The reason we are looking at 20,000 beds is not because we are saying that is how many we want to fill up. What we want to have are available beds for one very critical reason. If a young girl comes in, she is pregnant and has maybe a 2-year-old with her, and she is with her brother, we want to be able to have the capacity to put them together in a shelter and not have to say the child goes to a younger children's shelter. We need to have some flexibility in empty beds in order to get better care for these children.

Ms. DELAURO. At the high point, we were at 15,000. You are down to now, what, 11,000?

Mr. HAYES. Ten thousand.

Ms. DELAURO. Ten thousand. All the better. Numbers are going down, and that is not to say that they couldn't, but in 2014 our experience was when those numbers went down, they went down, it was through the September–October. They went down. I got a chart of that. You know, I don't make that up. So where is this 20,000 number coming from? You know, honestly, siblings are separated all of the time. We tried in the 2019 Labor-HHS bill to say that siblings could not be separated, but they are separated. We found that when we were at Homestead.

A child had a sister, a brother, or so forth, they were somewhere else, but that is no reason for trying to build an empire of beds. The goal should be, the focus should be, and we don't know where

this number comes from. Who projected this number? Where does it come, out of the thin air? What is the statistical basis on our having this there? You know, what are the resources? Quite honestly, the resources that you are devoting to ensure.

Where is the plan? You have a plan for 20,000. Where is your plan to ensure that children are placed with family members as quickly as possible? What case management services, Federal field specialists are part of your plan, and what protections will you put in place so that this Administration doesn't slow the discharge rate to a halt again? There is no comparable plan. You are at 20,000, but there is no comparable plan to move these children out as quickly as possible so we do not have to have an influx facility.

I am just going to add one more piece here, which is about Carrizo Springs. How is that contract structured with BCFS? Can we get a copy of that contract? Influx facilities are supposed to be temporary. I have seen one report that says 3 years, one report that says 5 years. And do you see a path for State licensing with Carrizo? And if not, why did you enter into a multiyear lease? So let's start with your plan for discharge, where the number 20,000 has come from.

Ms. JOHNSON. Based on looking at the trends over time and the number of children that have been placed into the influx facilities over time, should we have another surge in that same way, we do not want to have to open up an influx facility. So even if there are empty 20,000 beds, that is better than opening up a new Tornillo or a new Carrizo.

Ms. DELAURO. You by your own words here have said the high point is 61. You are talking to us about the numbers that are going down. At the highest point, you had 15,000. Fifteen thousand. And all of a sudden out of thin air comes a 20,000 number.

Ms. JOHNSON. If we were only to have 15,000 beds available at that time, we would not have had the flexibility to address siblings, pregnant teens, tender age because you can't place those children in with teenagers. You have to move them around. We need some movement.

Ms. DELAURO. You don't need another 5,000 beds to do this. What you do need to do, which I understand, and I am surprised you all haven't mentioned it, with your new grantee, you are looking at an additional 3,000 permanent State licensed facilities is what I have read about. So why are we not moving in that direction? When is the next recruiting for, you know, for grantees? But you have got now 10,000. You have got an additional 3,000. That gives you 13,000 potential beds. Why are we talking about an additional 7,000 when at the high point we are only at 15?

Ms. JOHNSON. The permanent licensed beds are much less expensive and are better for these children.

Ms. DELAURO. Yes.

Ms. JOHNSON. So if I don't have that additional beds available in a surge, we are back to influx, and I never want any Administration to have to go back there. In addition, may I say, the operational directives that we have done are also enhancing and moving the discharge rates.

Ms. DELAURO. Yes.

Ms. JOHNSON. We are taking these efforts. You just said it yourself, we have 3,000 new permanent licensed beds coming online. We are not ignoring the priority of licensed beds nor the discharge.

Ms. DELAURO. I am not saying that. I want you to focus your time and attention and any of the resources that we provide here to moving in that direction as we try to in the House bill on the supplemental, and what people want to say is that we held back. We held back not because of we did not want to provide the money. Every single day we talked about the \$2,900,000,000. What we wanted was the protections for these children and a discharge plan, and those two pieces are what we still want and what we still need. And we still do not have an adequate discharge plan for how we are moving that. You talk about a lot of beds, but let's talk about how we are getting them out as fast as we can and make a difference so that we do not have to have unlicensed facilities which are putting kids and their families at risk. And I have gone way over time, so.

Mr. COLE. Thank you very much, Madam Chair, and those are questions. They were questions that needed to be asked, so please don't feel like you went over your time. I want to actually build a little bit on what you talked of because I have some of the same concerns, probably from a different perspective. But I think you have those concerns as well. I mean, I think you would agree, I think, with all of us up here, regardless of perspective on the current thing, the best thing is to get these kids out of your custody as quickly as possible into an appropriately-vetted, you know, sponsor. Is that correct? That is your policy? That is what you are trying to do?

Mr. HAYES. Yes, sir.

Mr. COLE. And in terms of the surge capacity, and, I mean, I sort of understand it. I have had to live through this in my own district at Fort Sill, may have to live through it again. We are hopeful since there is a decline in the intake right now that perhaps you won't need to press that facility, but I certainly understand your need to have them available if something happens, you know. And I am not sure what that appropriate balance is.

I think the chair raises a good question. I don't know where that figure 20,000 came from either and I am not saying that critically of you. But that would be helpful to this committee if we got some sort of information on that, and I would certainly support the chairman's efforts to do that. And I hope you can enlighten us in that.

Second, I am very encouraged by this effort to also line up when State-inspected facilities and beds are available again. I think we all believe that would be better if we run into another surge than what we have had to deal with with influx facilities. And it strikes me that is your position, too. Am I correct?

Mr. HAYES. Yes, sir, you are.

Mr. COLE. Okay. And is there any additional information on both this target and what you see as the appropriate balance between, you know, facilities that are permanent, you are using all the time, others that would be licensed but would be available on relatively short notice should you need them, and finally and last resort al-

ways an influx facility? Do you guys have some sort of plan laid out where you sort of think through what the progression is?

And believe me, I say this with a lot of sympathy. I understand this is an unpredictable thing. We have had the budget up here. This committee has struggled really for years trying to figure out what is the count going to be next summer, what should we do, and know that, thank goodness, that whether it was the last Administration or this, you had a certain amount of flexibility and transfer authority. But even then, we have gotten the mark wrong with the best intentions in the world in having lived through one of these things before.

Mr. HAYES. So I just would add, sir, you know, first off, it is up to 20,000 beds is our goal, not just this magical number of hitting 20,000, but up 20,000. And I just will point out more from an operational perspective, which is more my lane as opposed to the assistant secretary's. And honestly, once you exceed kind of that 90 percent capacity of your permanent shelters, it does get very difficult to place children in permanent capacity because beds come online and go offline for various different reasons.

We might have a bedroom of, you know, 10 beds go offline because one child in there is quarantined, for an example. And all the UAC that come across the border that are referred to us are not created equal, you know. If we have a teenage brother and a younger sister, then that is going to be a very unique shelter that we want to place them in because we do not separate siblings at HHS. In fact, that will sometimes delay placement because we want to work hard with our grantees and our intakes team to find the most appropriate shelter for that person.

So, you know, as we look at, you know, the high mark that everyone's mentioned of almost hitting 15,000 children in care, I would hope that if I hear the number that I have 15,000 children in my care as I did almost back in early December, then I would hope that I would have had a minimum of 2,000 extra beds in order to help ensure that children will be able to be put in a permanent licensed bed as they are referred to us from DHS, and that we are able to do that as quickly as possible within that 72-hour mark.

Mr. COLE. That is good, and that is helpful. Thank you.

Mr. HAYES. Yes, sir.

Mr. COLE. I have got very little time left, so I just want to ask you, if I may, and either one of you or both can address the question. But could you just for the committee's edification explain some of the factors you have to deal with when you are actually making a discharge decision? What process has to have occurred before that? I am sure there are various iterations of this depending on the type of person, the age, the gender, you know, do they have special needs, et cetera, et cetera.

Mr. HAYES. Yes, sir. One of the one of the key things that our case management team focuses on is, you know, is the sponsor able to meet the needs of this child, medical needs, emotional needs, financial needs? Are they able to give them shelter and food? Do they have the, you know, the ability to help them, you know, get them plugged into the local community? And also, you know, again just to those kind of things to make sure that they are going into the safest environment possible.

We also do a very robust public records check on every single sponsor. Even the moms and the dads, and more distant family members and any of those family friends that the families have said, you know, would like the child to go and stay with this family friend they have a connection to, we are doing FBI fingerprint background checks on them just, again, to make sure that the child is going to the safest environment possible.

So while it is a very streamlined process, there are a lot of, you know, things that we work through. And I tell you, one thing I would suggest is possibly maybe sharing the sponsorship reunification package with this committee. There might be some information that needs to be redacted on it. I would have to check with our team, but that is something I am very much open to, again, in coordination with my leadership at HHS.

Mr. COLE. Okay. Thank you very much.

Mr. HAYES. Yes, sir.

Mr. COLE. Thank you for the time, Madam Chair.

Ms. DELAURO. Thank you very much. I say thank you to the ranking member. I want to just clarify, and to the credit of HHS, last December there were 15,000 children in detention. And because of that operational directive, almost within several days, 4,000 children were released to a sponsor or to a shelter.

Mr. HAYES. If I may, it was actually 8,000 in 30 days.

Ms. DELAURO. Well, to our point, if we can do that with the directives that you are engaged in, we do not need to continue the complexity of this detention system that we have, and that we want to move people into the safest possible space expeditiously. With that, Congresswoman Watson Coleman.

Mrs. WATSON COLEMAN. Thank you, Madam Chair. The Homestead facility has been in existence and in use since when, November of last year?

Mr. HAYES. So the original site was chosen. The contract awarded in December.

Mrs. WATSON COLEMAN. I am not talking—

Mr. HAYES. I don't know exactly what month, but it was in early 2016 when it was first operated with children.

Mrs. WATSON COLEMAN. Is there any legal prohibition stopping a facility of this nature becoming a permanent facility, getting a license?

Mr. HAYES. No, there is no prohibition, ma'am, and that is something I am open to consider. Again, again it would require a partnership with the local State—

Mrs. WATSON COLEMAN. And that is another question I want ask you. Do you think that it makes sense that you had Federal licensing regulations because the facilities that you are talking about, even the permanent ones, are only housing children, so they are technically Federal facilities, are federally-controlled facilities, or federally-existing facilities? Would it make more sense to have Federal licensing requirements that were uniform across the Nation?

Mr. HAYES. You know, I would be happy to have that conversation with you in coordination with the child welfare experts at ACF, ma'am.

Mrs. WATSON COLEMAN. All right. The facility, the Carrizo Springs facility?

Mr. HAYES. Yes, ma'am, Carrizo Springs, Texas.

Mrs. WATSON COLEMAN. Okay, it was open in 1 month and closed another month?

Mr. HAYES. It is not closed, ma'am.

Mrs. WATSON COLEMAN. According to this article I have, it is shut down. So what does that mean?

Mr. HAYES. Well, I am not sure exactly which article. I know—

Mrs. WATSON COLEMAN. Are you shutting it down?

Mr. HAYES. First off, we have not placed any child at an influx shelter since July 17th because we are below 85 percent capacity.

Mrs. WATSON COLEMAN. Are you shutting Carrizo down?

Mr. HAYES. I do not have plans to shut it down completely at this time. I will say, ma'am, just real quick, it had 41 kids there this morning as of 7:00 a.m., so it is not shut down, just to confirm that. I am not sure what the—

Mrs. WATSON COLEMAN. So you have a \$308,000,000 contract with them through January?

Mr. HAYES. That is up to—

Mrs. WATSON COLEMAN. Up to? But right now it is just the \$775 or \$800 per child that you are paying?

Mr. HAYES. The estimate there is just over \$600 right now is initial estimates there.

Mrs. WATSON COLEMAN. So you—

Mr. HAYES. It has capacity of about 1,100.

Mrs. WATSON COLEMAN. So you said that there were no children there, and now you are telling me there are 41 children.

Mr. HAYES. I never said there were no children there. I am telling you as of this morning there are 41 children at Carrizo Springs shelter in Texas.

Mrs. WATSON COLEMAN. So where is this information coming from in this article that you are shutting it down?

Mr. HAYES. I am not sure. We have had a lot of tours out there. Again, I think maybe it is coming from the perspective that, again, we are not placing children at any of our influx shelters anymore. We are working to draw those down. And because we are historically discharging children at high numbers, you know, the need for children to remain there is not an immediate need. Again, I don't know what is going to happen this fall, though.

Mrs. WATSON COLEMAN. Are there issues there regarding health and safety violations, mold, structural issues, things of that nature, unsanitary—

Mr. HAYES. No, structural issues, no. Once we initially purchased that, there was some mold in some of the buildings, but we brought in professionals—

Mrs. WATSON COLEMAN. You mediated that.

Mr. HAYES. And we absolutely, positively remediated it those issues before we had one child or any staff in there.

Mrs. WATSON COLEMAN. Thank you. Let me ask you one quick question.

Mr. HAYES. Yes, ma'am.

Mrs. WATSON COLEMAN. The background checks that are done for permanent staffers, is that the same as done for the influx staffers, too? Do they go through the same rigorous—

Mr. HAYES. I can tell you that the FBI background checks were done for the staff at Homestead and at Carrizo Springs.

Mrs. WATSON COLEMAN. Okay. If a child is placed in your facility and is 17 years old, 17-and-a-half, or whatever, do you do any kind of planning for that child? Do you try to find a sponsor before that child turns 18? Do you have any ability to hold on to that child if you are actively engaged in the search process rather than turning the child back over to ICE?

Mr. HAYES. The answer is yes and then no. Yes, we absolutely focus with every fiber in our being to do as much as we can for that child just as quick as possible. But as soon as that child turns 18, our statutory authority ends at HHS. And as I have mentioned several times on the tours and here today, if it were solely up to our grantee staff and our ORR folks, we would keep those kids as long as it took to find them—

Mrs. WATSON COLEMAN. So then turn them over and you notify ICE at certain periods. Is that like 30 days before they 18 years old?

Mr. HAYES. Again, they are referred to us from DHS, so DHS knows their age when they come to us.

Mrs. WATSON COLEMAN. Do you actively remind them this one will be 18 in 30 days, this one will be 18 in 10 days? Who, you got 24 hours?

Mr. HAYES. I would not describe it that we actively remind them, but we do work on a plan with them because there are certain different options that ICE can do. And, again, any further questions about that, I will refer you to my colleague.

Mrs. WATSON COLEMAN. And you have no idea what ICE does with them when it takes them back into custody?

Mr. HAYES. Once they leave our custody, statutorily, they go into the care of ICE. There are a lot of—

Mrs. WATSON COLEMAN. You said something that I thought was very interesting or either I read it in one of your testimonies that when you place children with permanent sponsors, with sponsors, that you do offer follow-up services, social services, any other kind of, you know, navigation that is necessary.

Mr. HAYES. There are some post-release services available.

Mrs. WATSON COLEMAN. You do that even though the child is no longer under your jurisdiction?

Mr. HAYES. Yes, ma'am, and I will just add, too, we have an ORR call center that is operated 24 hours, 7 days a week. And if any of our sponsors after the child goes into that care or the kids have any concerns or they are struggling with some issues, we can help find resources to help them out.

Mrs. WATSON COLEMAN. Madam Chair, just one last question. Thank you. Why does it cost 3 times the amount of money to house a child in an influx facility versus a permanent facility, even though that influx facility is in existence for more than a year? Thank you, and after you answer that, I will yield back. Thank you.

Mr. HAYES. So great question, ma'am. Thank you for asking it. I would say, and I am just going to oversimplify, but I think it gives us a high level of flexibility to both turn on and turn off staff and capacity at these influx shelters that does not exist at a per-

manent shelter. So with that flexibility and that ability to, again, turn on beds and turn off beds in order to bring the kids quickly and safety into HHS care and custody does cost more than a standard licensed shelter because we have very little, if any, flexibility at a permanent license shelter. If the State licenses it to be 122 beds, we can't add one more bed to that permanent facility without the State's blessing through a variance.

Ms. DELAURO. Thank you. Before I turn to Mr. Pocan—

Mr. HAYES. I can't hear you, ma'am.

Ms. DELAURO. I am sorry. Notification emails to ICE are sent, these are 18-year-olds—this was on the bulletin board at the facility—14 days away from the 18th birthday, 7 days away from the 18th birthday, and 24 hours prior to birthday. The information is sent to ICE to let them know about the 18-year-olds. Mr. Pocan.

Mr. POCAN. Thank you, Madam Chair. Yeah, actually a suggestion, Madam Chair. I find it surprising that there is a bit of a disconnect between the information you are sharing with Homeland Security and then knowing what they do with it, the fact that I asked you that day and again today and we don't have exact answers what they are doing with it. Madam Chair, it might be a good idea to have a joint hearing with Ms. Roybal-Allard's committee because not only am I curious, but I hope would you be curious, right? Because if I was a firm selling people's data and they use it to scam people on the front end of your business, that is one thing. But since our mission is, as the secretary said, as a child welfare agency, I would want to know because if the data we are sharing actually leads to fewer people coming forward a sponsors, that affects the child's welfare.

So I think you would all benefit from knowing that. I am kind of surprised you don't already have that information, and in the time you have been there you haven't asked for that information. But I do think it would be helpful for the committee and for you all to know, especially since some of it isn't required by law. I really think that might be a good suggestion.

Let me get back to that \$750 a day because I have been a small businessperson since I had hair, right? I was 23. I opened up a small business. So when I look at what we are paying, it still doesn't make sense to me because even if we know we are going to have this certain number we are preparing for, a permanent facility would be State licensed and have some better standards overall. And if it is a third of the cost, you really have to have some really highly-inaccurate projections to not save money by having full-time facilities as opposed to an influx facility that has been around as long as it has, right? Because that amount of money for no real education, not really providing mental health services—anyone would argue you are supposed to at the level that we should—it just still doesn't make sense to me that we would spend that kind of money when all of a sudden in the last few weeks, all these people got placed. That doesn't pass the smell test.

You know, for a long time, as you said, you have brought the amount of days down considerably, but what is the incentive to a firm to get people placed when they are making \$750 a day? And, again, they are a business, right? I appreciate some of the nonprofit groups that are operating things and they have a different mission.

But when you are a business, your mission is to make money, which means to continue to warehouse kids for as long as possible because you are making money. And if you don't have an incentive for them to actually place folks, that is completely counterintuitive to the free market, period, full stop.

So just respond to that. It just doesn't make sense to continue to have a facility that you pay 3 times the rate with worse conditions when there is no incentive for them to move people. And they just proved, as we started looking at things, suddenly 1,400 kids got placed in the matter of a month.

Mr. HAYES. So, again, specifically to your question, sir, I think that has everything to do with the Fourth Operational Directive. And what we are doing with that operational directive, and this was a recommendation that I received from the field out in Texas in one of my near 50 visits to our shelters. It actually came from one of our case managers. And that was, look, a lot of these children that come into our care have grandparents and adult siblings, you know, that are very close to them. So for a reason we have, again, based on the recommendations from the child welfare experts in our field.

Mr. POCAN. Sure.

Mr. HAYES. So that is what I would directly attribute—

Mr. POCAN. So then if I can, just in conversation with you, based on that directive, and I agree. That was a good idea, and I am glad you implemented that. Why do we even need this influx facility anymore, because now if that is directive, we can utilize the permanent facilities much better that are a third of the cost and have better conditions? Again, why have this privately-run, for-profit, more expensive than the Trump hotel or a Four Seasons operation when we could have a better operation for a third of the cost?

Mr. HAYES. That is a great question, Congressman. So first off, that is what we are doing. We are working to decrease the census at Homestead just as quickly and safely as possible. I don't know that I would support incentives for, you know, our grantees just to discharge children as quick as possible. I don't know that I would necessarily assign—

Mr. POCAN. I guess what I am saying is you wouldn't need incentives if you had cheaper facilities that had better conditions, right, you would be operating. But under this current thing, when I talked to that girl who was there 60 days or we look at the old rates of how long people were there, and we saw you can move people just by being innovative, they have no reason to be innovative. They have a reason to warehouse kids because that is how they make money because they are a for-profit venture.

But you are a child welfare agency to your very words. You have an incentive to not waste taxpayers' money, and to make sure the kids are in better facilities, and get them hooked up with sponsors, but we haven't done that for the last year, year and a half. So you are finally doing something towards it, but I need to know that that is going to be a better direction, Secretary, than what we have seen because I don't think the last year and a half is something we ever want to use as an example of how to move forward.

Ms. JOHNSON. Thank you. That is the goal, and you have heard me say that over and over. The permanent beds and the flexibility

of permanent beds are critical. But you also heard me say the time it takes to license a permanent bed, and it all depends on the State, if they are willing to have our shelters in their States, it takes time. We are now finishing up, as you said, 3,000 new beds that have come online from May, and I am hoping to have them on in the next 3 to 6 months.

And this is a continuing FOA. I am not closing it. I am keeping this open so that we can continue to bring on permanent beds. And the real goal of this, as you are all very aware, with the FFPSA in child welfare, there is a reason to decrease congregant care facilities. And if they already have a licensed congregant care facility that provides the mental health care, I would be very interested in those. So we want to encourage States to let us use what has already been built and already licensed, and those operational directives are absolutely critical.

Mr. POCAN. One very quick final question. Would you make a commitment, Secretary, because I am a little troubled that you guys don't know exactly when you will share that data and what gets done with it, because, again, it may not be in the interests of child welfare. Will you make a commitment to personally get some of that information so that we know what you are doing with the data, whether or not it is counterintuitive to child welfare?

Ms. JOHNSON. I would make the commitment to talk to DHS about that, but I would really request that you ask DHS directly. I wouldn't want them assuming what I do with information they provide. I would rather not assume or take just one person's word on what they do with it. So I would highly request you ask my sister agency.

Mr. POCAN. Thank you.

Ms. DELAURO. Congresswoman Roybal-Allard.

Ms. ROYBAL-ALLARD. I am going try and get at least two questions in, so I would appreciate very short, but pointed, answers. I want to follow up on Congresswoman Clark and Watson with regards to those detainees, those children that age out and turn 18, because one day a person is a child in a protective environment, and the next day they are put in handcuffs like a criminal and taken to adult detention on their 18th birthday.

As chair of the House Appropriations Subcommittee on Homeland Security, I find this not only disturbing because there are alternatives to detention that are less costly and more humane and dignified, but because I have been told that one of the reasons that ICE takes these children into custody and into detention is because ORR case managers fail to create post-18 plans for these children while they are in ORR care.

And one example that I was given, and this was information that came out in a Senate hearing was that in 2017, ORR failed to give ICE 400 post-18 plans for these children that age out. And I would like to hear why this is happening, and what is it that prevents them from providing these aging-out plans which would make them make recommendations to ICE that a particular child would be eligible for alternatives to detentions or sent to a sponsor and not to the adult facilities that they are in now.

Mr. HAYES. Yes, ma'am, and I will just point out I am a father of five, and I have a 17-year-old daughter, and, you know, I share

that concern that one day they are a child, and the very next day they are adult. I would say, though, you know, I feel like to some degree we are hearing mixed signals. You all don't want us to coordinate with ICE, but now you want us to coordinate with ICE. And so——

Ms. ROYBAL-ALLARD. No, no, wait a minute. Two entirely different things.

Mr. HAYES. Okay.

Ms. ROYBAL-ALLARD. One is the sharing of information in which ICE has gotten information on other people in the household and have gone and rounded up members of the family that has prevented sponsors from coming forward. What I am talking about is providing a plan that is given to ICE where ORR is supposed to recommend that child is eligible for alternatives to detention, that they can be placed with a sponsor and so on. So don't even mix the two.

Mr. HAYES. Okay.

Ms. ROYBAL-ALLARD. Don't even mix the two. So my question is why is it that ORR is failing to provide these post detention plans?

Mr. HAYES. So I am not aware of that specific report, so I would like to see it. But you have my commitment I will go back and meet with my team, and if we have any of our staff at our grantees that are not meeting their moral obligation to do everything in their power to benefit these kids, especially ones that are going to be aging out soon, we will do everything in our power to rectify that.

Ms. ROYBAL-ALLARD. You know, and I find it very disturbing that when you have statistics like this where you are not giving these plans that you are not even aware of it.

Mr. HAYES. I don't know where you are getting those statistics, ma'am. That is why I would like to see that, and I would absolutely commit to you today that I will look into that as quick as possible with my staff.

Ms. ROYBAL-ALLARD. Okay. I still am surprised that you are not even aware that these plans aren't being put together. Just very quickly in the time that I have left, earlier this month, the Miami Herald broke a story about a teenager who lived in the United States for 15 years. After a routine traffic stop, the uncle who was driving was arrested and put into ICE custody. And the boy was eventually placed at Homestead in spite of the fact that he lived with his mother in the U.S. This is really disturbing because the mother, who was the legal guardian, was not informed as to where her child was.

And, you know, I can only imagine the agony that the mother felt when she tried to find her son. According to the news report, she said, and I quote, "I called his phone a thousand times, called his uncle, called the police. Nobody picked up. Nobody had answers. I thought that he was either dead or kidnapped." And then days later, after the mother had contacted, ICE, CBP, and a local immigration lawyer, and finally ORR, when she read in the newspaper about Homestead, she figured that maybe her son was there, she was able to locate him at the Homestead facility. And she stated that the only reason she was able to finally get a yes that he

was there was, and I quote, "It wasn't until I lied and told them that I knew my child was at Homestead that they confirmed."

So under what circumstances would a child living with a parent be referred to ORR? And is there some coordination with ICE or ORR or DHS that encourages the transfer of children to ORR custody after an interior enforcement action? And I just want to say this is just one example. Let me give you quickly another example. I spoke to a young girl in the Homestead shelter who had been there almost a month. She had been detained with her brother who was older. Her brother was with the mother, and she was still at Homestead, and she said she didn't know when she was going to be leaving. So when she was detained, she was with her brother. The brother is with the mother, but she is still in Homestead. So we know that she had a sponsor and she had been there almost a month waiting to be reunited.

So these are the incidents that raise, you know, all these questions. Homestead, they make a lot of money by keeping children. So can you explain what the process is and why this is happening?

Mr. HAYES. If I may, ma'am, I would say on the surface what you are sharing with me is concerning to me as well, so I share that concern. What I have found, though, is, you know, I have a lot of questions that come into my mind as well to lead me to learn more about that unique situation. Was the brother an adult? I don't know the answer to that question. If she was with her brother and he is an adult, that is not considered a separation. By statute, she is required to come into the care and custody of HHS and we run through the sponsorship process. So if there are some more specifics I will look at—

Ms. ROYBAL-ALLARD. Well, I think the more critical question is that—

Mr. HAYES. The coordination?

Ms. ROYBAL-ALLARD [continuing]. He was with the mother. They were detained together. He was with the mother and why wasn't she?

Mr. HAYES. Okay. Are you saying he was with the mother when they were all originally detained?

Ms. ROYBAL-ALLARD. No, no.

Mr. HAYES. Okay. So that is my question.

Ms. ROYBAL-ALLARD. She was in your Homestead facility—

Mr. HAYES. And he was—

Ms. ROYBAL-ALLARD [continuing]. And he was with the mother. She knew where her brother was, and she didn't know why she was still there—

Mr. HAYES. And they were probably, in theory, on the way to the mother together, and they were detained. Then, again, my assumption there would be that the brother is probably not a child. He was over 18, and, therefore, she was required as a minor to come into our care, and then we run through the sponsorship process. So really the fact that she came in with her brother is not really relevant in that fact. The question is what we were doing to quickly vet and ensure that the mom was capable to take the child. That would be the information.

But, again, there are questions that come to mind, and I am happy to look into that particular situation. I know you interacted

with her, but I want her to be with her mom just as quick as possible.

Ms. DELAURO. Congresswoman Lee.

Ms. LEE. Thank you very much. I wanted to go back to, well, first, the contractor. I want to understand. Comprehensive Health Services is the operator, right?

Mr. HAYES. Yes, ma'am, that is correct, Homestead as well as several permanent network—

Ms. LEE. Okay. So Caliburn International, what is the relationship?

Mr. HAYES. I don't know exactly when, but Caliburn has purchased and owns CHSI.

Ms. LEE. Okay. So they own, okay, because I am looking at one of their filings with the SEC, and I just want to quote what it said. "Broader enforcement in immigration policy is driving significant growth. The company also warns investors that the challenging and politically charged environment could adversely impact our share price." Do you understand the fact that this is a profit-making business and that it is driven by their share price, and that they are there to make money? And, in fact, I don't know if you have any other private companies running these centers, but what do you think about that just in terms of a profit motive company taking care of these kids?

Mr. HAYES. Well, again, we do have some other for-profit providers out there other than just CHSI. I don't have those specifically memorized. I know they are in the system. I would just say that I have interacted very closely with the leadership of CSHI specifically at Homestead. I have seen nothing in any of the work that the staffers do that indicates to me that they are driven by profit. I know that Comprehensive Health Services does a lot of medical type care as well for Customs and Border Protection. But, you know, other than that, again, I go back to 2015 when that contract was originally issued, it was an open and competed process against several type of both nonprofit and other profit groups, and they were awarded the contract.

Ms. LEE. You may not see that they are driven by profit, but corporate entities are driven by profit, and so their systems are based on the profit motive. I mean, that is just how it works. And so, in looking at Homestead and the feeling there, as I said earlier, it feels like a prison. It feels like a jail. The systems that they have in place are warehousing in a jail-like system. Why didn't they develop the systems based on more of a boarding school system or something that is more conducive to taking care of these kids until they can transition out and then having a structure in place to, well, I won't say "expedite," but to process these children more quickly if, in fact, that is their goal? And there is a difference between a jail structure, which I think I saw there personally, versus a boarding school structure.

Mr. HAYES. I just think we are going to have to respectfully agree to disagree, ma'am. I would not classify Homestead as a jail or a prison—

Ms. LEE. I am saying it may not be classified, but the environment, the lining up, being told this, being told that, the physical structure, you don't see that in a licensed facility, and you don't see

that in shelters where you have a more conducive environment for the child's mental and physical health.

Mr. HAYES. I think I would both agree and disagree with you, ma'am, respectfully. I would say that I do think you see a lot of structure at even our—

Ms. LEE. Structure is okay, but—

Mr. HAYES. But, yes, we had a high number of children at our influx shelters. That is the purpose they serve in order for us to be able to quickly move as many children as we can into our care to prevent them from being at Border Patrol stations.

Ms. LEE. But the feeling I almost got was, it almost appears that these children could be seen as borderline criminals. And that is not the message we want to send to these children who are traumatized, who will hopefully be living with their sponsors very soon.

Mr. HAYES. Absolutely.

Ms. LEE. And so by being treated by prison like, criminal like, I still say that the case management system in place has to have a big component that recognizes that as part of this, and then says, okay, we have a program to deinstitutionalize these children before they are released. I am saying released before they are sent to their sponsors.

Mr. HAYES. "Discharged" is the term we use.

Ms. LEE. Discharged, yeah.

Mr. HAYES. Listen, we may agree on the environment at Homestead, but I do share your commitment to doing what is best for these children. And so with your background and your expertise and your years of service in Congress, if you have ideas how we could better set up our case management and clinical social work, our team would love to sit down with your team and hear some of your ideas.

Ms. LEE. Okay. Well, I would love to meet with you—

Mr. HAYES. Absolutely.

Ms. LEE [continuing]. To share ideas, and with the organizations that we have talked to who have specific protocols that they would like to recommend to you.

Mr. HAYES. I think that is a great idea.

Ms. LEE. Okay. Thank you.

Mr. HAYES. Yes, ma'am.

Ms. DELAURO. Let me give you a chance to respond.

Ms. JOHNSON. I would like to add on to that. For-profit or non-profit, we have our own monitoring guidelines. We have our own audits. We have external groups that go in and look at what is going on. So I would expect, as the assistant secretary over this program, that it doesn't matter their compliance, whether it is for-profit or non-profit. They are to meet the standards that we set, and that if they aren't, and we will continue to look at that because we can always do better in everything we do, we will move forward. But because they are for-profit, we don't monitor them differently. We are still very strict in our standards.

Ms. LEE. Well, you need to because they are for-profit, and profit is the motive by which they operate under.

Ms. DELAURO. Thank you to you, Madam Secretary, and to you, Director Hayes, for the time. It has been well over a couple of hours, and you have been forthright in your commentary. Just one

point because you are going to leave and we have another third panel coming up. I want to ask them to come up. But the contract with regard to Carrizo, and if we could get that contract as well as the Homestead, that would be terrific, and thank you. We do look forward to working with you in various ways.

Ms. DELAURO. I will repeat my hope is that, and just in terms of summarizing, Secretary Johnson, you support terminating the MOA, which is what you said. And my hope is that, Director Hayes, coming around to that will be critical for you, though I think, you know, you didn't answer that question. But I think that that has been one of the most serious and onerous policies emanating from that MOA that has brought us to the brink of something that has been, yes, a crisis, a humanitarian crisis. It did not have to happen.

Understanding what you have done in terms of rescinding some of those pieces, let's rescind the rest of it, and let's get these children with good standards of care and licensed standards of care, and U.S. and international law standards of care, as well as discharged as quickly as we can to their families, relatives, and a placement that is safe while they continue to go through the process. Thank you very, very much for being here this morning.

We are going to ask our third panel to come forward.

[Pause.]

Ms. DELAURO. Thank you very, very much, and I want to thank you for your patience, but I think it is important that we hear from you. There is a record, and fortunately I wish there were more of the members. But we have your testimony, and as I say, that this information is part of the record, and so you can be sure that it is distributed. So thank you again for your patience.

Let me introduce our panel. Margaret Huang ho is the executive director of Amnesty International USA, who recently published a report, "No Home for Children: The Homestead Temporary Emergency Facility." You have advocated before the United Nations as well as the Inter-American Commission on Human Rights. Earlier in your career you served as committee staff for the Senate Foreign Relations Committee.

And I would say this to you, Margaret. We are not going to hold it against you that you worked in the Senate. Is that not true, my colleagues? Okay, true. So thank you so, so much for being here. And to Krish, I want to make sure I get it right. Krish O'Mara Vignarajah. Yay, okay.

Mr. VIGNARAJAH. It is a tough one.

Ms. DELAURO. President and CEO of Lutheran Immigration and Refugee Services, LIRS, who has served as policy director for First Lady Michelle Obama. In addition, served as senior advisor of the State Department under Secretary of State Hillary Clinton and Secretary of State John Kerry. At the State Department, Krish coordinated development and implementation of multiple programs, including those concerning refugees and migration.

Now, I also understand that your dad is here. Is that correct?

Mr. VIGNARAJAH. He is indeed.

Ms. DELAURO. Where are we? Hello, yes. Thank you. Thank you. Now I got to get this one right, too. Eliathanbi? Okay. And so thank you so much for being here, and I know you sit there with

a great deal of pride, so it is wonderful to have you here today. So and I would just say to both of you, your full written testimony will be entered into the hearing record. Ms. Huang, you are now recognized for 5 minutes.

Ms. HUANG. Thank you so much.

Thank you for having me testify before you. My name is Margaret Huang, and I am the executive director of the U.S. Section of Amnesty International. We have advocated for the safety and freedom of children seeking protection here for the last years 20 years. Most recently, Amnesty International published our grave concerns about the Homestead child detention facility in Florida where thousands of children have been warehoused as they await reunification with their families.

Today's hearing is very timely and a critical opportunity to examine the conditions in which migrant children seeking safety here are being held, including the prolonged use of influx facilities like the Homestead Detention Center. As a starting point, under both U.S. law and international standards, detention is never in the best interests of the child and it should be avoided whenever possible.

In those rare situations when detention is truly necessary, it should be for the shortest amount of time and in the least restrictive setting.

The administration has increasingly relied on influx facilities to warehouse children because of crises that it has created. First, it continues to rip children apart from their families at the border, literally creating unaccompanied children who must then be placed in the custody of ORR. Over 700 families have reportedly been separated since the June 2018 order prohibited family separation.

A particular problem is the ongoing separation of children from their adult caregivers and family members. In many cases, these caregivers, grandparents, uncles and aunts, and adult siblings, are functionally parents to these children, and the separations are enormously traumatic. This is a stark violation of those children's best interests.

Second, this administration is prioritizing immigration enforcement over children's well-being. Under the Information-Sharing Agreement that you so ably addressed earlier with the previous panel, ORR is sharing information about the immigration status of children's potential sponsors with DHS.

Originally, this included all of the adults in a potential sponsor's home and we know that DHS is using this information to target sponsors for immigration enforcement.

The Agreement forces sponsors to make an impossible choice. Either they come forward and they free their child from detention and they risk being deported or they stay back and they let their children languish in detention.

After the Agreement was signed, the length of time that kids were spending in ORR custody nearly doubled. Because that policy has now been amended with operational directives, most recently in June, today thousands of detained children have been reunited with their families, and I've just come back from both Homestead and Carrizo Springs and was informed by the officials in those facilities that they attribute the sudden release of these children to the change in policy. It is not because it was not possible before.

To respond to this crisis of its own making, the Administration has resorted to using warehouses, like influx facilities, for longer and longer periods of time for some of the most vulnerable people in its care.

Homestead is only nominally temporary because it's been in operation for more than 16 months. Homestead is not a home. It's an industrial line for the processing of mass numbers of children. Children walk around with bar codes around their necks in a highly-regimented setting. They fill out forms to get the most basic of services.

Case management and medical treatment are inadequate. One child we spoke with found out that he was HIV-positive while he was at Homestead and he was kept in medical segregation for a month.

Facilities this large warehousing this many children cannot do right by the kids. Because Homestead is an emergency facility, it evades state oversight and their employees do not have to go through the same background checks as state-licensed shelters do.

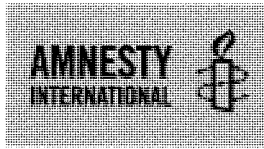
We must do better by these children who are coming here in search of protection. First and foremost, children should not be detained. Congress should prioritize funding policies and programs that keep families together and reunite detained children as quickly as possible with their sponsors.

Secondly, we must cease the protracted use of influx shelters and close Homestead, which is not in the best interests of the children. We have to prioritize funding permanent state-licensed small-sized facilities instead and only use those facilities when they're actually necessary.

Influx facilities should not be used for crises of the Administration's own making.

Thank you for holding this important hearing today.

[The information follows:]



**Written Testimony of Margaret Huang
Executive Director
Amnesty International USA**

Submitted to the
Subcommittee on Labor, Health and Human Services, Education, and Related Agencies
House Committee on Appropriations

For a hearing on "Oversight of the Unaccompanied Children Program: Ensuring the
Safety of Children in HHS Care"

July 24, 2019

Chairwoman DeLauro, Ranking Member Cole, and Members of the Subcommittee:

On behalf of Amnesty International USA and our two million members and supporters in the United States, I thank the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies for the opportunity to submit this testimony.

Today's hearing is a critical opportunity to examine the conditions in which migrant children seeking safety here are being held, including the protracted use of influx facilities, which are utterly unsuited to properly care for this vulnerable population and are yet being employed far beyond the temporary, emergency situations for which they are envisioned. The administration is increasingly relying on influx facilities to house children in large part because its own policies needlessly prolong their detention.

Rather than placing children in warehouse-like facilities and tent camps, the administration should prioritize their speedy release and reunification with loved ones, as both U.S. and international human rights law require.

Amnesty International's Engagement on the Issue of Child Detention

I am the Executive Director of the U.S. country section of Amnesty International, the world's largest grassroots human rights organization, comprising a global support base of over eight million individual members, supporters, and activists in more than 150 countries and territories. Amnesty International engages in activism, research, policy advocacy, litigation, and education to demand human rights for all people – no matter who they are or where they are.

Both our global movement and the U.S. section have advocated for the freedom and safety of migrant children seeking protection in the United States for close to two decades. A top priority for the U.S. section of Amnesty International is the protection of the right to seek asylum, which is under relentless attack. We have documented the harmful impacts of "metering" at ports of entry, the misleadingly named "Migrant Protection Protocols," and the abomination of separating asylum-seeking families and children.¹

In this context, we have observed with concern how the administration has weaponized the detention of asylum-seeking families, adults, and children to deter and punish the act of seeking protection. I have personally visited and documented conditions in each of the industrial-scale "influx facilities" constructed under this administration, including the infamous tent city in Tornillo, Texas; the warehouse-like facility in Homestead, Florida; and a newly opened campsite in Carrizo Springs, Texas.

¹ Amnesty International, USA: *'You Don't Have Any Rights Here': Illegal pushbacks, arbitrary detention and ill-treatment of asylum seekers in the United States*, Oct. 11, 2018, <https://www.amnesty.org/en/documents/amr51/9101/2018/en/>.

Following field visits in April and July 2019, Amnesty International published a report titled *No Home for Children: The Homestead 'Temporary Emergency' Facility*, which documents our concerns about the prolonged detention of children in the Homestead facility in Florida.² The report concludes that the government is violating the human rights of thousands of unaccompanied children by warehousing them in a facility it claims is “temporary,” but in reality, has operated for 16 months and counting. Our report urges the closure of Homestead as soon as possible and the immediate release of children detained there to families, loved ones, or – as a last resort – permanent, state-licensed, small-scale ORR shelters more appropriate for their care and wellbeing.

Standards Governing the Detention of Children in Domestic and International Law

Each year, violence and persecution force thousands of children to come to the United States. These children are seeking asylum or other forms of humanitarian protection under U.S. and international law. They are among the most vulnerable people in our government's care.

Children who arrive at the U.S. border alone, or who are separated from their parents or caregivers at the border, are considered “unaccompanied” and typically transferred from the custody of the Department of Homeland Security (DHS) to the care and custody of the Office of Refugee Resettlement (ORR) within the Department of Health and Human Services (HHS), where they are housed until they can be released and reunified with a “sponsor” – typically a parent or close family member.

Under U.S. and international law, the touchstone of any decision concerning these children must be the principle of the best interests of the child. As a starting point, and as reflected in the binding *Flores* agreement, family unity is generally always in a child's best interests and must be prioritized wherever possible – meaning the administration's practice of ripping apart children from their parents and caregivers at the border and prolonging the detention of those children in facilities, instead of expeditiously reuniting them with family members in the United States, are stark violations of this principle.

Detention is never in a child's best interests, and children thus should generally never be detained for migration-related reasons. Under international law, individuals can be deprived of their liberty only when their detention is provided by law, necessary to fulfill a legitimate objective, and proportionate to that objective. In the exceptional circumstances where detention of children complies with these requirements, both *Flores* and international law require that it should be for the shortest time and in the least restrictive setting possible.³

Flores further requires that where release to a child's family or loved ones is not possible, children must be held in non-secure facilities that are licensed by the appropriate state

² Amnesty International, *No Home For Children: The Homestead 'Temporary Emergency' Facility*, July 18, 2019, https://www.amnestyusa.org/wp-content/uploads/2019/07/Homestead-Report_1072019_AB_compressed.pdf.

³ *Flores v. Lynch*, No. CV 85-04544 DMG (Ex), Central District of California, 21 August 2015, <https://www.aila.org/File/Related/14111359p.pdf>.

child welfare agencies or entities. The Trafficking Victims Protection Reauthorization Act (TVPPRA) similarly requires that children be placed in the “least restrictive setting that is in the best interest of the child,” and notes that children “shall not be placed in a secure facility absent a determination that the child poses a danger to self or to others.”⁴ Children in government custody generally must have access to legal representation, telephones, health care, counseling, education, recreation, and religious services.

Notably, *Flores* provides exemptions to these standards “in the event of an emergency or influx of minors into the United States.”⁵ By operating influx shelters indefinitely, the government is exploiting this loophole and evading state oversight and basic requirements for child shelters.

Administration Policies Have Jeopardized Family Unity and Prolonged Child Detention

Though domestic and international law require family unity to be preserved wherever possible, the government has adopted practices that do exactly the opposite: jeopardizing family unity and needlessly prolonging child detention by separating caregivers from children and implementing an information-sharing agreement between DHS and ORR that places potential sponsors at risk of deportation. These practices are not only antithetical to the principle of the best interests of the child; they have also proliferated the use of “temporary emergency” facilities when the only “emergency” is a crisis of the administration’s making.

- **Separation of Caregivers and Children at the Border**

While the cruel and illegal practice of family separation was nominally halted by a court order in June 2018, children continue to be separated from their parents, legal guardians, and adult caregivers upon arrival at the U.S. southern border, and thus become functionally “unaccompanied” even when they were accompanied by a loving family member or caretaker when they arrived.

Over 700 families have reportedly been separated since the date of the court injunction halting family separation and May 2019.⁶ This is because the government appears to be exploiting a loophole in the order that permits the separation of children from their parents or guardians for certain limited reasons.⁷ Further, agents at the border continue to separate children from adult caregivers who are not parents or legal guardians, ignoring the cultural context of these families, in which many of these caregivers are functionally these children’s parents.⁸ The “Migrant Protection Protocols” have also

⁴ 8 U.S.C. § 1232(c)(2)(A).

⁵ William Wilberforce Trafficking Victims Protection Reauthorization Act (TVPPRA) § 235(c)(2); 8 U.S.C. §1232(c)(2), Pub. L. No. 110–457, 122 Stat. 5044 (2008).

⁶ Michelle Goldberg, “The Terrible Things Trump Is Doing in Our Name,” *The New York Times*, <https://www.nytimes.com/2019/05/21/opinion/family-separation-trump-migrants.html>.

⁷ *Id.*

⁸ “US: Family Separation Harming Children, Families,” Human Rights Watch, July 11, 2019, <https://www.hrw.org/news/2019/07/11/us-family-separation-harming-children-families>.

contributed to the separation of children from adult caregivers, who are forced to wait in precarious conditions in Mexico until the conclusion of their cases.⁹ A recent report found that the forcible separation of non-parent caregivers “appears to be a routine practice” because the administration is interpreting these children to be “unaccompanied” under the terms of the TVPRA.¹⁰ However, DHS’s own regulations give it the discretion to release children together with adult caregivers.¹¹

Not only are family separations abusive and traumatic, they also create unaccompanied children out of accompanied children. Lawyers who visited the infamous Clint Border Patrol station observed that many of the children held in filthy, neglectful conditions there initially came with family members from whom they had been separated.¹² An attorney representing migrant children in ORR custody to whom Amnesty International spoke in Texas described the difficulty of providing legal representation to children in custody who had been separated from caregivers: “When I speak to them about their cases, all they can think about is, ‘Where’s my uncle?’”

Instead of separating hundreds of children from their caregivers, which irreversibly traumatizes families and needlessly places children in government custody, the administration should preserve their unity wherever possible. Decisions to separate children from caregivers should be made only by trained child welfare professionals and only in the exceptional cases where unity would not be in a child’s best interests. Reunification of children with their families – the primary project of ORR’s migrant child program – is necessary only where the unity of those families is broken in the first place.

- **The DHS-ORR Information-Sharing Agreement**

Even though most children in ORR custody, including at Homestead, have family members or other sponsors to receive them, a new policy that prioritizes immigration enforcement over child welfare has led to their prolonged detention.

Under an DHS-ORR information-sharing agreement signed in April 2018, ORR has continuously shared a broad range of information on unaccompanied children, including their potential sponsors, with Immigration and Customs Enforcement (ICE). The agreement is a departure from prior ORR policy and practice to place unaccompanied children with the most appropriate sponsor without consideration of the sponsor’s immigration status for enforcement purposes.¹³

⁹ Women’s Refugee Commission, “New Report Reveals Danger of Remain in Mexico,” May 16, 2019, <https://www.womensrefugeecommission.org/news/press-releases-and-statements/3536-new-report-reveals-danger-of-remain-in-mexico-including-new-cases-of-family-separation-confiscated-identity-documents-new-inhumane-cbp-custody-tents>.

¹⁰ See *supra* note 8.

¹¹ 8 C.F.R. § 236.3.

¹² See *supra* note 8.

¹³ See National Center for Youth Law, Center for Human Rights and Constitutional Law, and the University of California Davis School of Law Immigration Clinic, *The Flores Settlement Agreement & Unaccompanied Children in*

The DHS-ORR agreement and subsequent immigration enforcement based on that agreement has chilled the willingness of potential sponsors to come forward and drastically delayed the placement of unaccompanied children with sponsors.¹⁴ Children's average length of stay in ORR custody nearly doubled following implementation of the policy, from 48 days to an average of 75 days.¹⁵

In December 2018, ORR acknowledged that the policy had delayed the timely release of unaccompanied children without benefiting children's safety.¹⁶ It dropped the requirement that all adult members of a potential sponsor's household be fingerprinted, and now does not require fingerprinting of parents, legal guardians, grandparents, or adult siblings.¹⁷ As a result, average lengths of stay at Homestead have plummeted from close to 90 days before the policy changes to approximately 25 days as of July 2019.

However, the information-sharing agreement remains in effect, meaning sponsors will continue to be afraid to come forward. The FY 2019 Department of Homeland Security appropriations bill signed in February 2019 prohibits ICE from initiating enforcement actions against a potential sponsor or sponsor or members of their households based on information shared by ORR. However, the bill's broad exceptions still enable ICE to potentially use information obtained from the DHS-ORR agreement to target sponsors or their household members for immigration enforcement.¹⁸

Influx Facilities Like Homestead Are Not in a Child's Best Interests

The temporary influx facility in Homestead, Florida, is one of two such facilities currently operating in the country; the other is a recently opened facility on the grounds of a former "man camp" for oil workers in remote Carrizo Springs, Texas.

When it opened in March 2018, Homestead was designated as "temporary," yet it has functioned more like a permanent shelter for 16 months and counting. During our April

Federal Custody at 12 (Feb. 2019) (hereinafter "*Flores Report*"), <https://youthlaw.org/publication/the-flores-settlement-agreement-unaccompanied-children-in-federal-custody>.

¹⁴ R. Moore, *Thousands of Migrant Children Could Be Released with Trump's Major Policy Reversal*, Texas Monthly, Dec. 18, 2018, <https://www.texasmonthly.com/news/trump-fingerprint-policy-change-reduce-migrant-children-detention-tornillo/>.

¹⁵ L. Kriel, *Longer stays leave record number of immigrant children in detention*, Houston Chronicle, Nov. 21, 2018, <https://www.houstonchronicle.com/news/houston-texas/houston/article/Thanksgiving-in-immigration-shelters-as-number-of-13415048.php>.

¹⁶ R. Moore, *Thousands of Migrant Children Could Be Released with Trump's Major Policy Reversal*, Texas Monthly, Dec. 18, 2018, <https://www.texasmonthly.com/news/trump-fingerprint-policy-change-reduce-migrant-children-detention-tornillo/>.

¹⁷ See, e.g., National Center on Youth Law *Flores Report*; Women's Refugee Commission and National Immigrant Justice Center, *Children as Bait: Impacts of the ORR-DHS Information-Sharing Agreement*, March 2019, www.womensrefugeecommission.org/images/zdocs/Children-as-Bait.pdf.

¹⁸ House Joint Resolution 31, Consolidated Appropriations Act 2019 § 224, Feb. 25, 2019, <https://www.congress.gov/116/bills/hjres31/BILLS-116hjres31enr.pdf>; see, Tal Kopan, *Funding deal blocks ICE from arresting adults taking in undocumented children*, San Francisco Chronicle, Feb. 14, 2019.

2019 visit, the facility was straining at the seams, with well over 2,000 children in its care. Its population has since reduced and, as of this writing, stands at under 1,000. At the beginning of July, the facility stopped accepting children to reduce its size to no more than 1,200 children to shelter in place for hurricane season.

Both influx facilities currently in operation are large-scale settings unsuited for the care and shelter of unaccompanied children. Homestead has the look and feel of an industrial facility, composed of permanent and semi-permanent structures on a North and South Campus, which have at points warehoused thousands of children. Hundreds of children sleep in bunk beds on a single floor on the North Campus, and all children must wear ID cards with barcodes around their necks as they walk from place to place.¹⁹ Carrizo Springs similarly has the capacity to house over a thousand children in trailers in a remote setting, though it currently houses fewer than 200 children.

Because of its designation as a “temporary emergency” facility, Homestead has evaded obligations placed on permanent, state-licensed shelters. This has meant that thousands of children have been warehoused in a facility that is not adequately centered on the best interests of the child principle.

Below are some of the chief concerns Amnesty International identified at Homestead:

- **Prolonged and Indefinite Detention of Children for Profit**

While recent policy changes have been a step in the right direction, the prolonged and indefinite detention of children at Homestead remains a serious concern.

When Amnesty International first visited Homestead in April 2019, the average length of stay was over 52 days, and some children had languished in the facility for 100 to 200 days at a time. While, as noted above, the average length of stay has now reduced to 25 days, prolonged detention at Homestead is still a serious concern for children, particularly those who do not have close relatives to sponsor them.

Prolonged and indefinite detention is particularly detrimental for 17-year-old unaccompanied children, who represented a majority of the unaccompanied child population at Homestead when Amnesty International visited in April and July, and who are at risk of “aging out” of the facility and into adult detention. While Homestead has a dedicated case management team which works to expedite the release of any children within 90 days of their 18th birthday, children who are not released are subjected to the traumatic experience of a “birthday arrest,” where they are taken from ORR custody into adult detention the day they turn 18.²⁰

¹⁹ See Flores Agreement, para 12(3); see *Flores v. Lynch*, 212 F. Supp. 3d 907, 914, Central District of California, 2015, *affirmed in part, reversed in part and remanded*, 828 F.3d 898, 9th Circuit, 2016.

²⁰ John Burnett, “Migrant Youth Go From A Children's Shelter To Adult Detention On Their 18th Birthday,” NPR News, Feb. 22, 2019, <https://www.npr.org/2019/02/22/696834560/migrant-youth-go-from-a-childrens-shelter-to-adult-detention-on-their-18th-birth>. Though ORR policy requires unaccompanied children not to be placed at a temporary emergency facility if they will turn 18 within 30 days of the transfer, Amnesty International learned that children have

The prolonged detention of children at Homestead is particularly troubling when considering its operator, Comprehensive Health Services, is part of Caliburn International, a for-profit corporation that stands to directly profit from the prolonged detention of children. Indeed, Caliburn's board members include former DHS Secretary John Kelly, who promoted policies prolonging the detention of children while in office. Detention at both influx facilities currently in operation is extraordinarily costly: between \$750-\$800 per day, per child, compared to approximately \$250 per day in a licensed, permanent shelter. However, in contrast to Homestead, the not-for-profit corporation operating the Carrizo Springs facility told us that its goal is to shut down its influx operation as quickly as possible, ideally by the end of July, because influx shelters should be a "last resort," reserved for true emergencies.

- **Evasion of State Oversight**

While *Flores* requires all ORR facilities to secure state licensing from state child welfare agencies, Homestead is exempted from this requirement both because it is designated as a temporary influx care facility and because it is on federal land.²¹ The continued categorization of Homestead as "temporary" facility – despite its prolonged operation – has thus enabled it to circumvent state welfare regulations critical for ensuring the safety of children in government care. The lack of state licensing and oversight has meant that the contractor operating Homestead can bypass running background checks on staff against Florida's child abuse and neglect background check system. All staff of any ORR facility housing children must be properly and thoroughly vetted, without exception.

- **Conditions at Odds with the Best Interests Principle**

Available services and the conditions of Homestead – including the facility's rigid institutional nature, educational services, language services, remote case management services, and systems to report allegations of sexual abuse – fail to center care based on the best interests of the child.

First, the facility's **industrial size and highly regimented setting** is a far cry from the "least restrictive setting" principle outlined in *Flores*. Homestead provides care in a large-scale, warehouse-like environment with thousands of children adhering to highly regimented schedules, who are deprived of individualized care, attention, and freedom to be children.

Due to its sheer size and scale of operation, Homestead has the feel of a secure detention facility, not a small-size group home or residential setting that is centering the

been transferred to Homestead shortly before turning 18 years old, and have been transferred to adult detention as a result.

²¹ Administration for Children and Families, *ORR Guide* § 1.7, available at www.acf.hhs.gov/orr/resource/children-entering-the-united-states-unaccompanied-section-1#1; see *Flores* Agreement, para. 12(3).

child's best interests. Children wear ID badges with barcodes that they must scan as they enter and leave buildings, and they follow chalked lines when they walk outside. The barracks-style residences further contribute to the feel of a detention center. Daily life and services are highly regimented, with children's schedules tightly controlled from 6:30 a.m. to 10:00 p.m., with only an hour and 50 minutes of free time. Children must request any services – from sanitary pads to psychological counseling – via a "service request form." Children interviewed by Amnesty International who had been held at Homestead complained of the strict and rigorous rules imposed on them at the facility.

By contrast, permanent shelters generally provide small-size residential settings designed to feel like homes, not detention facilities. One Honduran teenager who had been transferred from Homestead to a permanent shelter noted that the biggest difference she perceived was the intimacy of care she received in the permanent shelter: she was able to spend more time playing and felt more comfortable sharing details about herself with staff. Given the trauma many of these children have faced and their distinct vulnerabilities, they should be placed in drastically less restrictive settings than Homestead.

Second, while **education** is a critical right for children, temporary influx facilities are only required by ORR to provide that right "to the extent practicable."²² While Homestead does provide educational services, they are deficient. Instruction takes place in large, noisy classroom settings. Education instructors are not certified and use a curriculum created by the corporation running the facility, while nearby ORR shelters (and even the other temporary facility in Carrizo Springs) require teachers to be licensed by the local county. In April 2019, when we visited a school classroom, children were being instructed in math, but there was not a single textbook to be seen: instead, children were copying the words of the Pledge of Allegiance. Since Amnesty International's visit in April, a head manager of education services had been hired, and individual classrooms seemed more child-centered, though the noise was still clamorous.

Third, lack of adequate access to **language services** particularly disadvantages children who do not speak English or Spanish. Homestead staff informed Amnesty International that, while the facility will identify Indigenous language speakers for transfer, children will not be transferred if they can communicate in Spanish or English. This is troubling given that nearly half of children detained in Homestead are Guatemalan, many of whom likely speak Indigenous languages as their first language. This approach to Indigenous and non-Spanish, non-English speakers is inadequate: relying on a child's ability to communicate in a secondary language fails to protect their best interests.

Fourth, Homestead is providing inconsistent and inadequate **case management and social services** for children in its care. Case management teams include caseworkers who focus on the child's release to sponsors as well as clinicians, who provide counseling

²² *Id.*

services to them. Homestead has aggressively expanded its use of remote case management services, which have often resulted in inadequate and impersonal care. Nearly a quarter of all case management teams at Homestead at the time of our April visit were based in Texas, meaning that children communicate by video with their case management team, including their clinicians. While children can request an in-person visit with their clinicians, they must do so via a request form.

Remote case management has been detrimental for the children held at Homestead. One 17-year-old boy who had been diagnosed with tuberculosis upon arrival was held at Homestead for eight months and assigned a remote case manager based in Texas despite his vulnerability. Another boy discovered that he may have been held much longer than necessary, as his remote case manager falsely told him that she was speaking to his sponsor every day. In three months, this boy met with his case manager only three times.

Similarly, medical care has at times been inadequate at Homestead. Amnesty International spoke with two boys who were both diagnosed with HIV after arriving at Homestead. In one case, the boy's sponsors dropped out after learning of his HIV-positive status. In one case, Homestead personnel kept the boy in medical segregation for a month, and doctors told him not to tell anyone else about his status. Given the incredible vulnerability of children like these, remote case management services and impersonal care are utterly inadequate.

Finally, the **system for reporting allegations of sexual abuse** is insufficient. According to media reports, there have been at least six or more allegations of sexual abuse at Homestead, including two involving staff members, since the facility opened in 2018.²³ Despite this, Homestead fails to provide adequate privacy for unaccompanied children to report allegations of sexual abuse. At the time of Amnesty International's visit in April, in one area housing 17-year-olds, children who wished to report abuse were directed to use an open-air cubicle, within five feet of a ping-pong table in a recreation room. While the ping-pong table was later moved, this improvised cubicle demonstrated the inherent problems in a facility designed to warehouse children rather than root practices in their best interests.

Recommendations: Towards a System Where Children and Families are Together and Free

- **Family unity must be prioritized in legislation and policy.** Both Congress and the administration must prioritize reunification of migrant children with family members and sponsors as a paramount goal. The administration should rescind policies that categorically separate children from adult caregivers. For its part, Congress should legislate protections ensuring that children are not separated

²³ CBS Miami, *State Probed Abuse Claims At Child Migrant Shelter In Homestead*, March 20, 2019, <https://miami.cbslocal.com/2019/03/20/state-probed-abuse-claims-at-child-migrant-shelter-in-homestead/>.

from caregivers and should invest in hiring more staff to expedite release of children to their families and other sponsors, including increasing the numbers of ORR Federal Field Specialists.

- **The Homestead influx facility must be shut down as soon as possible.** Homestead is an industrial line for processing children, not a shelter for children. We laud efforts that have been made to reduce its population and urge the administration to close it in full as soon as possible and release children to their sponsors.
- **Congress must prioritize funding for licensed, permanent, small-scale facilities, as influx shelters should truly be a measure of last resort.** HHS should develop a far-sighted planning process that has the elasticity and responsiveness necessary to accommodate variations in the numbers of unaccompanied children. Congress should ensure that funding for ORR facilities prioritizes licensed, permanent, small-size shelters that can more appropriately care for children, and that influx facilities are used only for true emergencies, not as the new default standard of migrant child care. Temporary emergency facilities should always be state-licensed, built at a smaller scale, and adhere to U.S. and international human rights law. Congress should also invest in increased psychological and psychosocial care in ORR facilities, including by increasing the number of clinicians available per child.
- **Congress should invest more resources in long-term care for children who truly cannot be reunified with families or sponsors.** Several advocates described to us the challenges faced in securing long-term care for children who have no sponsors or family members in the United States and whose cases often fall through the cracks. Rather than needlessly detaining children who have sponsors, the administration should dedicate shelter resources to care for those children who do not have sponsors, including through long-term shelter placement programs.
- **The DHS-ORR information-sharing agreement should be rescinded in full, and congressional appropriations should restrict without exception all enforcement actions based on information shared via the agreement.** The administration should rescind the DHS-ORR agreement in full, and Congress should place limits on FY2020 DHS spending bill to ensure that no dollars go to enforcement based on information obtained in the agreement. Congress should also pass the *Families, Not Facilities Act* (H.R. 2217), which would prohibit enforcement actions taken on the basis of information gleaned in the information-sharing agreement.
- **Congress should place limitations on funding for contracts with for-profit corporations, as they will not be properly incentivized to care for children.** The detention of children should not be a business. Congress should place strict limits on ORR's ability to contract with for-profit corporations to ensure that corporations are not wrongly incentivized to cut corners and prolong child detention, particularly detention in influx facilities ill-suited to children's care.

Ms. DELAURO. Thank you very, very much for your testimony. And now, Ms. Vignarajah.

Ms. VIGNARAJAH. Thank you, Congresswoman DeLauro, Ranking Member Cole, and distinguished members of the committee, for the opportunity to testify.

The organization I lead, Lutheran Immigration and Refugee Service, has a long history of successful collaboration with the government through 80 years of work in refugee resettlement, our care for unaccompanied children, and our ongoing management of family reunification. We work with partners, like Reverend Wilker from Lutheran Church of the Reformation.

During last year's family separation crisis, LRS was one of only two organizations asked by the government to help with family reunifications. Neither LRIS nor our sister organization, the U.S. Conference of Catholic Bishops, received any government payment for that work, but without a moment's hesitation, we stepped up to respond based on an unwavering commitment to family unity and ensuring all God's children are welcomed, protected, and offered love and warmth, not concrete floors and Mylar blankets.

The term "unaccompanied minors" is seemingly meant to give the impression that these children come to the border by themselves. It masks the fact that some are unaccompanied because we stripped them from their parents' arms. So it is my duty to report that the assertion that family separation has ended is not true. In fact, we have nearly 40 children who were separated even after the policy supposedly ended, four of them tiny babies, less than one year old. They were not unaccompanied minors until our government made them so.

As a faith-based organization, we believe no child should be separated from a parent in order to deter other parents. As a faith-based organization, we believe no child should be held hostage as bait in order to subject family members to fingerprinting for immigration enforcement purposes, and so we request the formal end to the Memorandum of Agreement between the Department of Homeland Security and Health and Human Services. We were heartened to hear the Assistant Secretary's testimony on that fact.

We are trying desperately to reunite families and this Agreement has significantly impeded parents and other sponsors from coming forward and prolonged the time that vulnerable children are separated from their family.

But our efforts to reunify families are much broader and that is the focus of my testimony today. Right now, some children are being housed in large shelter facilities that face allegations of sexual and physical abuse. Some are kept in a Walmart turned warehouse among nearly a thousand other children. Others are in a federal influx facility where a 144 children sleep in one room with no state regulation and little oversight.

So what if I told you what you know, that there is an alternative, that I could provide many of these children with a loving set of foster parents who could offer a child not just shelter but a safe and stable home, that this care could help the child reunify with their actual family safely and more quickly, and that in the interim, these nurturing foster care parents would help the child learn, read, play sports, tuck them into a warm bed at night, and that

this care would cost a third or a half of the price of warehousing children?

As a parent or grandparent, wouldn't you choose the family-like setting? And as an appropriator, wouldn't you choose the setting that is better for kids, better for taxpayers?

Well, this choice isn't theoretical. It's the one government faces every day when it places a child in a temporary influx facility like Homestead rather than a family setting like the care that LRIS provides.

This year, we've already cared for 549 kids. Yet as large shelters grow, we have loving foster care parents today with empty homes. Remarkably less than half of the care that we've offered to the government is being utilized at this moment.

How is that possible? Well, here's what we're up against. Right now, private prisons and for-profit companies account for over 70 percent of the immigration bed facilities in this country. We know the government's extraordinary logistical burdens but caution against settling for the convenience of for-profit influx and detention facilities.

These entities are not guided by the best interests of the child but by the best interests of their shareholders.

As criminal justice reform has pushed private prisons out of the American penitentiary system, they've turned to immigration to turn a profit and profit they have. Caliber and the company that runs Homestead earn \$775 per child per day. Since 2018, they've received contracts for \$545 million.

Just as I was visiting Homestead, Caliburn was trying to sell a hundred million in stock and said the need to house migrant children is "projected to drive growth," as Congresswoman Lee pointed out.

Today's testimony has shown that they are not qualified to care for children, let alone traumatized migrant children. So rather than a Homestead, how about a home instead? For 40 years, LRIS has established proven models of family and family-like care for unaccompanied minors until they can be reunited with their families, a model of care that is small, safe, and family-centric.

We ensure children receive trauma-informed care and that all our foster parents and caseworkers are licensed by the state and receive up-to-date information on the new child welfare standards because we must never forget that these children are not just in our custody, they are in our care and while they are that burden of responsibility of protection, of oversight, sits here with American leadership and the power you wield.

Thank you.

[The information follows:]



**Lutheran Immigration
and Refugee Service**

House Appropriations Subcommittee on
Labor, Health and Human Services, Education, and Related Agencies

**“Oversight of the Unaccompanied Children Program:
Ensuring the Safety of Children in HHS Care”**

Written Testimony of
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July 24, 2019

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Good morning. Thank you Chairwoman DeLauro, Ranking Member Cole, and distinguished members of the Committee for the opportunity to testify.

Today's hearing comes at a pivotal moment in immigration history, at a time when daily we are seeing images of the heartbreaking suffering of vulnerable migrant children. But this is not a problem without solutions. My testimony today concerns the moral and legal imperative we face as Americans, and as people of faith, to put the best interests of these children first.

My testimony focuses on recommendations that will ensure the physical and psychological health and well-being of these children while they are in our custody. LIRS has decades of experience in policy and programming with children who come into the immigration enforcement system in the United States. We are a solutions-oriented organization that works closely with our Federal partners and a national network of local affiliates to ensure every child who enters the United States is treated with the dignity and care that we would wish for our own children.

We recognize that all children are children of God and through our services and advocacy, we stand committed to protecting the children's best interests as enshrined in domestic and international law – and as dictated by common human decency.

First, all places where children are in the care of the government - whether temporary influx facilities, group homes, or processing centers along the border – must adhere to strict child welfare standards, including ensuring appropriate child welfare staff who are vetted and licensed, and whose fundamental aim is to ensure timely, safe family reunification.

Second, because it is in the best interests of a child to be placed in the least restrictive setting, LIRS strongly urges that the default placement for children be in small group homes or with foster families as soon as practicable, until they can be reunited with family or other sponsor.

Third, it is imperative that we decrease the time it takes to safely reunify children with their families or other sponsor. If a child has no family or contact here, we must ensure these children are cared for in appropriate long-term foster care settings.

LIRS's Decades-long Role in Providing Care for Vulnerable Migrant Children

LIRS is a faith-based, national non-profit organization with over 100 partners in 39 states across the country. For 80 years we have supported refugees from around the globe. For over half this time, LIRS has provided child welfare services to migrant and refugee children who are unaccompanied or separated from their families. We are one of nine refugee resettlement agencies and one of only two agencies approved to work with unaccompanied refugee minors in America. We were also one of only two organizations asked by the government to help reunify families after the “zero-tolerance” family separation crisis last summer¹. LIRS and our partners serve migrant children and their families and refugees by offering transitional and long-term foster care, family reunification services, border support services for asylum seekers, and share best practice experience and technical knowledge.

¹ LIRS and United States Conference of Catholic Bishops/Migration and Refugee Services. (October 2018). “Serving Separated and Reunited Families: Lessons Learned and the Way Forward to Promote Family Unity.” Available at: https://www.lirs.org/wp-content/uploads/2018/10/Serving-Separated-and-Reunited-Families_Final-Report-10.16.18-updated.pdf

The Effects of Family Separation and Inappropriate Conditions at the Border

Protections such as the Flores Settlement Agreement (FSA) exist to ensure that the “best interests of the child” are upheld while children are in government custody. The harmful chaos created during the zero-tolerance policy that led to separating thousands of children from their families without any plan for reunification is anathema to this nation’s values and an abdication of modern-day child welfare protections. Numerous studies have demonstrated the long-term effects of adverse childhood experiences (ACEs) on children’s developing neural networks and their physical health. Although the zero-tolerance policy was officially rescinded on June 20, 2018, we are deeply troubled by the fact that we continue to encounter such cases.²

While recognizing the jurisdiction of this Committee, we also believe there are a set of commonsense solutions that could help end unnecessary family separations, avoid placing children in influx shelters, and improve the overall conditions of confinement, so that children are not unduly traumatized prior to children entering ORR custody.³

Small, Safe, and Family-Centric Transitional Foster Care is the Gold Standard for Unaccompanied Children

LIRS and our partners are dedicated to making decisions based on the best-interests of the child: preserving family unity, ensuring children are cared for in the least restrictive setting, and prioritizing the safety and well-being of these children.

² We also continue to be troubled today by disruptive border policies such as “metering,” Migrant Protection Protocols and the July 16, 2019, asylum Interim Final Rule (IFR) that authorizes asylum officers to deny asylum to asylum seekers—including unaccompanied children-- if they transit through a third country.

³ Please see Recommendations, Appendix A.

LIRS is a grantee of ORR and through our national network we provide group homes, transitional foster care (TFC) as well as long-term foster care – many of our children are in the care of over 400 loving foster care parents. I am proud to say that LIRS transitional and short-term foster care service providers serve unaccompanied children as if they were their own.

I will focus on our group homes and TFC program and how it is associated with our family reunification services. LIRS partners operate both group homes and TFC for vulnerable unaccompanied children. Per ORR requirements, our group homes meet state licensing requirements, are small in scale, with an average size of 12 or fewer children, and are staffed 24/7. Prior to placing an unaccompanied child in a foster home, we ensure that all foster parents are state-licensed, and trained per state law, and with additional training in cultural orientation, trauma-informed care, and an overview of U.S. immigration proceedings. Our aim is simple-- provide a home-like environment to children until they can be reunified with their families in the United States.

To streamline the reunification process, LIRS offers ORR-funded Safe Release support services, which includes working with family members of unaccompanied children and sponsors to obtain: background checks, fingerprinting, document assistance, and community service referrals to ensure the family gets the social services the child and parent or sponsor need.

The Effects of Temporary Influx Shelters

LIRS understands the federal government is reacting to an unprecedented number of unaccompanied youth seeking refuge in the U.S. But we must ensure that children in U.S. custody are not just in our custody, but in our care, and that the conditions are conducive for their safety and well-being.

I was part of a faith-based delegation a few months ago, touring Homestead, the largest children's "temporary" influx shelter. I was instantaneously struck by the stark contrast between our LIRS model of small, safe, and family-centric care compared to what I saw at Homestead. Our tour guides instructed us not to speak or touch children, claiming that it was in their best interests. At the time of my visit, we were told there were 1,694 children in Homestead. I observed cramped quarters of 144 children sleeping in one room, small rooms with bunk beds tightly packed in, to which our tour guide informed us that children preferred this because it was "like a sleep-over."

Homestead is problematic for many reasons. First, Homestead is run by Caliburn and its subsidiary Comprehensive Health Services (CHS); neither are experts in child welfare. According to HHS, CHS provides "medical management service" and, yet it has been placed in charge of "operating the child care and wrap-around support services at Homestead Shelter."⁴

Second, by virtue of its location--on federal land--and designation by the Department of Health and Human Services as a temporary influx shelter, Homestead

⁴ AFC, July 17, 2019. "Fact Sheet: Unaccompanied Alien Child Shelter at Homestead Job Corps Site, Homestead, Florida." Administration for Children and Families. Available online at: <https://www.hhs.gov/sites/default/files/Unaccompanied-Alien-Children-Sheltered-at-Homestead.pdf>

does not have to comply with the Flores Settlement Agreement and is exempt from state licensing requirements.

Third, children are quite obviously suffering psychologically and physically while inside Homestead. According to the findings in *Flores et al, v. Barr Case CV 85-4544 (July 12, 2019)*⁵, children expressed to Plaintiff attorney's "feeling hopeless, crying themselves to sleep, and self-harming" while in Homestead. LIRS recognizes that migration patterns ebb and flow and that when ORR is overcapacity and cannot offer children shelter due to lack of bed space, temporary overflow facilities are required. Homestead is not the solution. Moreover, it was opened in February 2018 and has been operating for nearly a year and a half, hardly temporary.

LIRS and our dedicated partners work hard to expeditiously reunify children with their families. The same cannot be said of Homestead. "In January, Flores co-counsel reported that 140 children had spent 100 days or more at Homestead, 26 children had spent 200 days or more there—more than 6 months."⁶

It is for all these reasons that LIRS will continue to grow our foster-care network to ensure temporary influx facilities are not needed.

Children in the Crosswire of Immigration Enforcement: Memorandum of Agreement (MOA) between DHS-HHS

On April 13, 2018, DHS and HHS entered into a Memorandum of Agreement (MOA), "*Consultation and Information Sharing in Unaccompanied Alien Children*

⁵ *Flores et al, v. Barr Case CV 85-4544 (July 12, 2019)* Available at <https://files.constantcontact.com/baccf499301/46b3af89-44e7-4084-8e11-9108879bec20.pdf>

⁶ Tanvi Misra, (July 22, 2019) "Inside Homestead: A Tour of the Florida Camp for Migrant Children, available at: [https://plus.cq.com/alertmatch/41755507870&deliveryId=50280890&uid=weeklyreport-5599998&utm_med\(ium\)=alertemail&utm_source=alert&openinplus=true](https://plus.cq.com/alertmatch/41755507870&deliveryId=50280890&uid=weeklyreport-5599998&utm_med(ium)=alertemail&utm_source=alert&openinplus=true)

Matters,” that went into effect on May 13, 2019⁷. Since it was introduced, the MOA has been attributed to the following chain of events: increasing the length of time children spent languishing in government custody, which has led to overcrowding and capacity issues at ORR shelters, which has then prompted ORR to open emergency influx shelters to address its bed capacity shortage. In short, since the MOA policy was introduced, children have had to stay longer in ORR care, prolonging family separation and in some instances, removing the option of family unification if a child’s only sponsor withdraws their sponsor application⁸. The MOA is another example of how a deterrence approach to immigration that fails to consider the best interests of the child harms children.

Prior to the MOA, ORR had the authority to share personal data collected during the family reunification process if requested by another government agency. Under the terms of the agreement, once CBP or Immigrant and Customs Enforcement (ICE) transfers a child to ORR, the agency is required to share with DHS all information with respect to “the vetting of potential sponsors and adult members of potential sponsors’ households; and upon release from ORR care and custody.”⁹

Through our Safe Release program, LIRS runs the majority of fingerprint sites across the nation. We have been monitoring the impact of the MOA at our fingerprint

⁷ ORR-DHS Memorandum of Agreement, available at: <https://www.texasmonthly.com/wp-content/uploads/2018/06/Read-the-Memo-of-Agreement.pdf>

⁸ LIRS, Women’s Refugee Commission, et al. Backgrounder: “The ORR and DHS Information-Sharing Agreement and its Consequences” available at: www.lirs.org

⁹ MOA, *Supra* note 6.

sites prior to and in the aftermath of when the MOA went into effect. Our results are as follows:

- **LIRS Data on Sponsor's Cancelling and/or Not showing up for Fingerprints:** For the period prior to the MOA (2/1/18-6/7/18) only 6 percent of sponsors cancelled or failed to show for their fingerprint appointments. After the MOA went into effect (6/8/18-9/30/18) the rate of cancelled appointments increased to 33 percent.
- **LIRS Data on Sponsors Declining to be Fingerprinted:** Prior to the MOA (2/1/18-6/7/18) 0 percent of our sponsors declined to be fingerprinted. In contrast, after the MOA went into effect (6/8/2018-9/30/18) 9 percent of sponsors declined to be fingerprinted.

LIRS's data suggests that the MOA has had a chilling effect on sponsors coming forward. As care providers, the "best interests of the child" and family reunification guide all of our policies. We oppose the MOA and similar deterrence policies that disadvantage children and inflict unnecessary physical and psychological harm.

On September 18, 2018, former ICE Executive Associate Director Matthew T. Albence testified to Congress that the MOA was the basis for arresting 41 sponsors. As of today, there have been 170 sponsors arrested as a result of the MOA¹⁰. So long as the MOA exists, it will continue to frighten away sponsors and leave children to languish for longer periods of time in ORR custody, in influx detention facilities like

¹⁰ House Committee on Energy & Commerce. "House Chairs Urge Trump Administration to Rescind Child Migrant Information-Sharing Memo. (July 3, 2019) Press Release. Available at: <https://energycommerce.house.gov/newsroom/press-releases/house-chairs-urge-trump-administration-to-rescind-child-migrant-information>

Tornillo and Homestead. Using children as “bait” for immigration enforcement purposes is an alarming and cruel practice and under no circumstances is it justified. Children deserve better from our government and deserve to be with their loved ones.

LIRS appreciates the measures ORR and Congress have taken to temper the MOA to make it less of an immigration enforcement tool. Collectively, ORR’s decision to remove the requirement for fingerprinting all household members, parents and immediate relatives and Congress’ FY 2019 Appropriations language that restricts DHS from using the information it receives from ORR to arrest sponsors, have had an impact. For instance, these changes have led to a reduction in the length of stay for children in ORR’s care. That being the case, LIRS has two concerns. First, the forms that sponsors are required to complete offer inefficient data protections, ergo, there is no way to guarantee that the sponsor’s information will not be transferred to ICE. Second, until the MOA is officially terminated, children will continue to be affected because their sponsors will not feel safe coming forward.

Thank you for this opportunity to address the Committee and I look forward to working together.

Appendix A: Recommendations

Lutheran Immigration and Refugee Service (LIRS) offer the following recommendations for the consideration of both the U.S. Department of Homeland Security (DHS), and the U.S. Department of Health and Human Services (HHS).

DHS

First, CBP should not separate families unless the following conditions are met: a qualified child welfare expert has identified a risk of trafficking by the parent or legal guardian; there is evidence of serious and imminent physical harm to the child; or parentage or legal guardianship issues arise that require additional investigation. In addition, we implore the government to put data systems in place to ensure rigorous documentation, tracking, and follow up on separations, including informing separated parents of how to contact their children, how to rebut the reason(s) for the separation, and how to seek reunification with their children.

Second, state-licensed professionals specially trained in the screening and care of children—not CBP officers—should evaluate children’s needs and conduct all relevant screenings that occur before a child is released or sent to HHS via the Office of Refugee Resettlement or ORR. These child welfare professionals can coordinate with state authorities if there are allegations of abuse or mistreatment. Any allegation or instance of abuse needs to involve local child welfare authorities, so the appropriate procedures and protocols are followed. Moreover, screenings should occur as soon as possible and CBP facilities without child-trained professionals on site should at least have on-call professionals available. These professionals could also conduct screenings for trafficking, fear of return, and flag or screen for any issues of safety or parentage -- including determining whether a suspicion of non-parentage requires follow-up or additional investigations.

Third, it is imperative that all children in CBP custody receive prompt medical screenings by qualified medical professionals who have expertise and experience working with children, including nurses and pediatricians. These specifically trained medical professionals can work alongside child welfare professionals to identify any additional medical needs requiring additional follow-up or care. This would include ensuring access to adequate food, hydration, and hygiene, dry clothing, regular showers, and other appropriate care. Further, the documentation of their medical care needs to occur regularly and be sent to ORR and eventually their in-country providers, like LIRS. These documents are often left with CBP, and not sent along. It is critical that ORR and its partners understand the medical issues and history of the children they are encountering—for the health and safety of all concerned.

In sum, LIRS' recommends that DHS:

1. Immediately cease unnecessary family separations;
2. Immediately improve the conditions of confinement for the care of children and ensure independent oversight in their facilities;
3. Immediately place licensed child-welfare experts into their facilities; and
4. Drastically improve the quality and timely delivery of medical care in their facilities.

HHS

LIRS recommends HHS:

1. Ensure that protocols and mechanisms are immediately put into place to ensure children placed in temporary influx shelters are there for the least of amount of time as possible;
2. Work with LIRS, and other similarly situated child-welfare and immigration experts, to create viable and practical child-centric standards for these facilities; and
3. Immediately rescind the MOU with DHS so the community chilling effects of this devastating document are stopped.

Ms. DELAURO. Thank you both very much for very powerful testimony and thank you for your dedication, your commitment, and compassion in dealing with this very serious issue.

Both of your testimonies highlight how toxic the MOA is for the UAC Program. Just a couple questions in this regard.

Can you tell us more about the chilling effect the MOA continues to have on the sponsor-vetting process, how this results in children staying in ORR care far longer than is healthy or necessary, and if HHS and DHS rescinded or terminated the MOA, do you believe you would see an immediate improvement in identifying sponsors? Please, I'll hear from both of you. Go ahead, Margaret.

Ms. HUANG. Thank you, Congresswoman. Thank you for the question.

We know that hundreds, perhaps at this point thousands of children have been released in the last month since the new operational directive was issued in mid-June, and all of the facility operators we spoke with, not just influx facilities, I should note also permanent shelters we visited on our trips, as well, they've all indicated that that directive had an enormous impact on all of them. They were immediately able to see their numbers go down. So it's very clear that the barrier is the requirement of fingerprinting and sponsors being afraid to come forward.

Unfortunately, we don't have data sufficiently from ICE about whether it is in fact targeting sponsors, how many people might have been identified and arrested because of the Information-Sharing Agreement. So that would be information that would be wonderful for Congress to seek.

I do believe that if we continue to see the removal of these obstacles as we perceive them that we would see more children unified.

When we visited the Carrizo Springs facility, all of the children who were sent there were sent from other shelters, from Texas and Arizona, and all of the children had Categories 1, 2, or 3 sponsors.

The day we were there, they learned that one of the children's sponsors had decided they could no longer come forward, which would make that child now a Category 4 child, and so there are still issues, even children who have identified family members here, if they're fearful of coming forward, which many of them still have that fear. It is actually forcing the children to stay much longer.

Ms. VIGNARAJAH. So I'll add to that the data that we do have. We provide the majority of reunification services across the country and so we interact with potential sponsors on a daily basis.

So we have data from four months before the MOA went into effect and then three months afterwards, small sample size but I think informative.

What we found was in terms of the number of cancellations and no-shows, it increased from six percent to 33 percent, so a third of these potential sponsors no longer came to our facilities.

In terms of declining fingerprinting, it went from zero percent, we had no declines, to nine percent, and, you know, I know that in the prior testimony, there was some question about what is the impact and why has it had such a chilling effect? It's because the reality that we know that even from data that was shared between July and November 2018, we had a 170 arrests based on that infor-

mation alone and so, you know, the chilling effect that we are observing in our facilities is being observed across the board.

So there's a public report that we put forth that indicated that 75 percent of the survey participants in terms of providers observed that fewer potential sponsors are now coming forward.

Ms. DELAURO. I'd very much like to get that report, if we can. Thank you.

Let me just ask a question to you, Krish. What is the LRIS preferred standard of care for unaccompanied minors?

Ms. VIGNARAJAH. So, you know, as I briefly touched on in the testimony and I appreciate the opportunity to speak a little bit more in detail, we very much believe that we can provide a care model that is safe, small, and family-centric.

Our model is really centered on child welfare best practices. It is designed around the recommendations of child welfare experts. Truly, it is a labor of love for us. It is not a for-profit center and so for us, the guiding principle is what's in the child's best interests?

For LRIS, we have numerous partners in states really across the country that operate the transitional foster care that I mentioned, which is truly a family environment, as well as very small group homes which are essentially family-like.

On average, our size is 12 children or less but the vast, vast majority of our placements of children are in transitional foster care in individual homes, and we believe that, to the extent possible, and really we do have the capacity that we should be affording every child, migrant or otherwise, with a loving family environment.

Ms. DELAURO. Thank you.

With that, let me recognize Ranking Member Cole.

Mr. COLE. Thank you very much, and thank both of you for your testimony which I read last night and enjoyed listening to again today.

Ms. Huang, if I may start with you, obviously you've got a study on Homestead. Now did you study it in the last Administration, as well, when it was first established?

Ms. HUANG. No, we did not, sir. In fact, I believe it was even opened prior to the dates that were mentioned by the director in the previous testimony. It was actually opened even in 2012–2013.

Mr. COLE. Yeah. That's what I recall, as well. Any particular reason why you didn't look at it then? It would be very helpful, and I'm not being critical in this, if we had kind of continuous study of what happened in what is clearly a controversy.

Ms. HUANG. It would be. I wish we had, but we didn't. We actually requested to visit lots and lots of shelters in the last 12 months. We've been given access to Tornillo. I visited Tornillo last fall as well as to the two I've mentioned, and we've requested and visited a number of permanent shelters.

We've not been granted any access to CBP holding facilities at all—

Mr. COLE. Okay.

Ms. HUANG [continuing]. Despite multiple requests.

Mr. COLE. Well, they're in very different categories obviously.

Let me ask you this. A lot of your testimony is very compelling about the separation of children and family members. Currently, the law of the land, as I understand it, is if you're not with a parent or a legal guardian, even if it's an aunt, an uncle, you know, somebody that we would consider an appropriate family member, is that a statute we should change? How would we approach that?

Ms. HUANG. Yeah. Actually, DHS has the discretion to keep families together if they're identified as such. I think there is a challenge if you're asking law enforcement officials to make that determination and I can understand why we would not want CBP to decide whether or not an adult and child traveling together are the appropriate pairing, but there are child welfare professionals who can make those determinations. That's what in fact ORR does, and if we allow those people to interview and to meet with potential families traveling together, they could make that determination and in fact CBP is not required to separate the child.

Mr. COLE. So would you—well, I think they would say we don't know if this is really an aunt or uncle. We don't have the appropriate papers. We don't know if this is something where a child has been encouraged to identify this person who may be a nefarious individual. There's got to be some mechanism for the child's sake to check here.

So right now, I think it's probably pretty automatic, I'm not sure, but I would assume that for Customs and Border Patrol to do that.

Would it be better to keep them together and then turn them over to DHS and where you would have this sort of option that you described?

Ms. HUANG. So ideally children should never be put in detention. That's what we're aiming for and the goal would be to try to keep the children with loved ones, with caregivers, to be able to make that determination with appropriate child welfare expertise, not by law enforcement, and then to enable those children to be allowed to pursue their claims which I believe most of these children have asylum claims, to allow them to pursue those claims not in detention but in fact with other means of showing up for their court proceedings, which a very high percentage of them do.

Mr. COLE. That's correct, but again I'm just trying to—it seems to me we've stumbled into a second crisis because we didn't learn very many lessons from the first crisis. That is, this is not news. Everybody up here said we've done this several times and we seem to be reinventing the wheel over and over and over again. Homeland's probably a pretty good example of that.

And yet we also have some concern about—which I have the same concerns my Chairman does over establishing regular institutions and maintaining them because our aim is exactly what you say, get them into an appropriate sponsor as quickly as possible, not let them stack up, whether it's at a Border Patrol facility or an HHS facility. Let's try to move these people through to a more appropriate place for them to be.

How would we do that? I mean, with the estimates of the crowd—you know, the folks coming very hard to predict. We've had really pretty dramatic swings. If you went back to the first year of the Trump administration, you'd see a dramatic fall, partly prob-

ably because of the rhetoric of the Administration, fear about coming.

I don't know if we have—and we have a different composition of population now and partly that's clearly cartels figuring out how to monetize the movement of human beings, in addition to drugs and what have you.

So I'm just looking for suggestions here. What sort of system would we need so that as these folks arrive—and by the way, I don't hold the administration responsible for that. I hold their home countries and cartels responsible for that. So I don't say they created the crisis. They may have mishandled the crisis. That's a fair point to make. I don't think you could say they created it. They're not—you know, they didn't do something to attract this population to the border.

So how would we have a system that works better than the one we have now where we're not each time ad hoc and give me just a little—I want both of you, if you'd care to respond.

Ms. HUANG. So I do think that one of the ways that Congress could be most helpful is really making the investments in the reunification efforts.

Right now, there are insufficient numbers of caseworkers working in all of these influx facilities. A lot of them operate remotely. They're nowhere near the children that they're trying to serve. There are not enough of the field agents who actually investigate to find the sponsors and to reunify them.

So there's a different approach and I know that Congresswoman DeLauro referenced that, to have a plan that makes investments in reunifying members. Even as you say, Congressman, if an adult and child approach the border and Customs and Border Patrol aren't sure if they're related, it's understandable and appropriate for them to make sure that they are before they're released together, but that process doesn't have to take months. It doesn't have to take the amount of time it's doing now.

So rather than investing in beds and these influx facilities, which are incredibly expensive, a much better investment is into making sure that that analysis is done, that the care is given, that the children are being released as quickly as possible into the care of those sponsors, and so I think the challenge for us is that the investments have been made more in the detention side, less in the reunification side and that's what we really want to be seeing.

Ms. VIGNARAJAH. It is a great set of questions and I think the way I'd approach it is to look at it as a sort of sequence.

Phase 1 is really when we're talking about DHS custody. What can we do to make less of a stark contrast between CBP custody and ORR custody, and, you know, a few of the recommendations—we included this in the Appendix knowing that it's obviously not the purview or jurisdiction necessarily of this committee is, you know, first, CBP is not following the policy of standards that they themselves have always had on the books, and I think that that is really important in terms of the conditions of confinement right now are problematic and we would just request that they actually review some of the policies that they have in place, that there be independent oversight of the facilities, which is natural in many other settings, that we introduce state-licensed child welfare ex-

perts into CBP facilities because right now we do have agents that are just by the nature of their training ill-equipped to be making determinations that are based on the best interests of the child.

But I would also say, you know, it's about timely medical care. There ought to be pediatricians. There ought to be nurses in these CBP facilities. We also believe that we need to start moving towards alternatives to detention. LRIS has been very involved in piloting and showing the success of family case management.

We know that there's been appropriation of funding for that and we would just really request that that money actually be moved to where it was intended.

In terms of that kind of middle area of when family separations is happening, one of our recommendations is that we don't get sufficient information because there is critical information that is lost in translation and so one of the things that we would really request is that in terms of the—there's a 213 document that tries to reflect information of it's not a parent, who is this individual, what is the relationship?

Oftentimes we find that ICE and ORR aren't getting that information. We're getting an individual with basically we have a name, an age, and a home country location. With that, it means that we're looking for a needle in a haystack and so any cooperation in terms of helping us facilitate that reunification process would be critically important.

Then the final piece just in terms of the facilities under ORR's purview, first and foremost, obviously we've made the case, I think, and there does seem to be bipartisan agreement in terms of fostering and appropriating funding for, you know, safe, small, family-like settings, but what we would also recommend is that we don't continue to experience this roller coaster.

We strongly believe that having the infrastructure of guaranteed multiyear funding is critically important, but we'd also stress that, you know, in terms of the ORR funding for grants management, some of the issues we've seen as an organization, even in the last couple months, is that we put in indication that we would be able to take in a 108 additional children two months ago. It was supplemental to a contract that we already have. We actually got approved for a new contract rather than the supplemental, which is just an example of where, you know, look, it's not a thousand, you know, beds that we're able to provide but it certainly is a 108 children that could be under our care as opposed to in an influx facility.

I think one of the things we'd strongly encourage is that ORR prioritize, you know, the grant management for facilities like ours as opposed to the influx facilities, and then the final point because, you know, I do take this point of what we are seeing is in some ways not new to this Administration.

Our firm belief is that it doesn't matter if it's a Republican or a Democratic Administration. We're helping children. It's completely inappropriate on American soil. The one thing I would note, though, is that, you know, to the extent that I've looked at it, it is clear that under the Obama Administration, there was kind of a more permanent part of Homestead. It's called the Old Job Corps site, which is where children were placed, whereas when I visited,

and you probably saw this, as well, the children are being placed in semi-permanent structures and it is that uncertainty, you know, kind of the non-permanent nature of that that does, amongst many other concerns, raise red flags for us.

Mr. COLE. Thank you. Thank you. You were very indulgent with the time. Thank you, Madam Chair.

Ms. DELAURO. No, thank you. I mean, your recommendations, both of you, this is what we need to have. This was the concern. We're willing to provide resources but not to continue the current process which is failing and more than failing, the repercussions on children are really staggering in so many ways.

I have no problem calling into question policies of the prior administration and that's why in this case, we are looking at some more restrictions around the process that has created a situation where we were trying to deal with increased numbers of immigrants, but the policies have had a significantly negative detrimental effect on children. So that's, I think, what we have to acknowledge in both administrations.

Let me just ask if you have a child with a Category 1 or 2 sponsor and that is parents or family, a family member, grandmother—and, you know, look, I come from an extended family. I understand that some of my aunts were like a mother, you know, an uncle, a father. You know, when my father passed away, my uncles stepped in. They all helped take care of me. That's what so many families are about today.

So if you have a child with a Category 1 or 2 sponsor, once the sponsor has been identified in your view, how long should it take to place the child safely? No one is suggesting cutting corners or doing it safely in your views. Go ahead, Margaret.

Ms. HUANG. We believe that 2 weeks should be sufficient—

Ms. DELAURO. Two weeks?

Ms. HUANG [continuing]. In that situation, yeah, and certainly under the Flores conditions, we believe that it is possible to be much shorter than the timeline it's taking now, but you all are the experts placing, so you should answer that question, too.

Ms. VIGNARAJAH. Yes, and I should, you know, on that point flag that I know there's a lot of discussion around length of stay and I want to just clarify that we shouldn't put all our eggs in that basket in the sense that length of stay reflects the amount of time for those children who are actually discharged, right?

So if we have an instance of 10 children, one child is discharged in 10 days, nine children actually remain in custody for a hundred days, your length of stay would be 10 days when in fact if you would actually contextualize it, it would be 91 days at that snapshot period.

So one of the things I want to flag is that, you know, I know there was some prior discussion about, well, under the Obama Administration, it was X days. Under this Administration, it has declined. As child welfare experts, our concern is making sure that we have as short a window as possible but knowing that background checks are in place for a reason and, you know, we are a little bit concerned about the fact that, you know, right now under the new regulations, this Administration doesn't even require, you know, a bona fide relationship being established.

There were reasons why those checks were put in place because we had instances of trafficking happened not 20 years ago but just two years ago and so I think that's where for us, you know, I think two weeks is a good aim but, candidly, for us, as long as we can get sufficient paperwork to support that this is in fact, you know, a family member and that we have conducted all the safety checks, we believe that it's possible to even do it in shorter amounts of time.

Ms. DELAURO. The bureaucratic snafu around—you know, I understand two weeks in the shortest particular time. Why then would it—why would it be taking so long in some of these instances?

I understand what you're saying. Why is it taking so long? And clearly it didn't have to take as long. We're witnessing within the last several weeks, yeah, that there is movement, there's real movement, and so there is—from your perspective, there is not a reason other than bureaucracy, there is no reason to hold up this process in getting these kids to family members, parents or relatives of some sort.

Ms. VIGNARAJAH. And I think, you know, the few points I would stress in terms of how can we reduce this time period to ensure the reunification of family is, you know, first, in terms of the reunification services we have where oftentimes with the potential sponsor, that's the first interaction with any kind of immigration entity.

It is quite clear that for many of these sponsors, it is critically important to have an in-person resource who can walk them through what is frankly, as this hearing reflected, it's a complicated process for any individual, even who, you know, has a mastery of the English language.

You know, second, I do think that we need to invest resources in making sure that the paperwork is available not just in English but in also the first language of the sponsor because we found that to be a hurdle in terms of why the paperwork is taking so long.

Third, obviously we've talked about the MOA in terms of the chilling effect, and then, fourth, as I've mentioned, we need to strengthen the information-sharing between DHS, ICE, ORR, and then the implementing organizations so that we can expedite that process.

We can do it. It's just a matter of streamlining and having better coordination between the different entities.

Mr. COLE. I'm really probably at that point, I have more observations than questions that would take a longer period of time, but I do want your thoughts on a couple of items because having lived through one of these things as the chairman and now having lived through another one as the Ranking Member, I don't want either of our successors to do this again.

So to me, part of the big problem is how do you set up a system that allows us to handle something that might not be predictable on an annual basis but is certainly something we know we're going to probably face again? It's almost like planning for a hurricane. You don't know when it and how but you know there's going to be hurricanes.

So there needs to be a better system than what we've had and I say that with no criticism of anybody involved. I think they've

handled the situation broadly as well as they could as they've gone on, but we've got to do a better job in Congress and as whoever the Administration is of thinking through what do we do when something like this happens.

So toward that end—and I will tell you one of my problems, I sit on the Rules Committee and we had a piece of legislation coming through that was getting ready to lay down a lot of requirements in terms of the border control and what do you do when you have an unaccompanied minor, perfectly appropriate for us to be talking about. There wasn't a single dime of authorization for more money, not a dime.

So we're going to consider something, probably pass it through the House, it won't get through the Senate, would never be signed by the President, but if you're going to do this, it's going to take resources, and particularly if you're going to change the nature of the Border Patrol.

I mean, even some of the suggestions you had about the types of additional personnel you would have at the border, they're really not designed by and large to be legal points of entry. They are Border Patrol. They're actually there to stop human trafficking, to stop drugs, to stop folks coming into the country illegally, and how you combine and give them the resources—we had the same, honestly, struggle when we did the authorization recently.

One of the points of contention was the Majority didn't want to give any additional money to the Border Patrol because they thought it would be used for Border Patrol purposes as opposed to being used for the kids. So I understand the concern there, but at the end of the day, you've got to get passed that. They either have the resources to do the things you suggest or they don't. They stay exactly like they are and that's probably going to take authorization language and its stuff beyond our ability in this subcommittee.

But I would just again ask both of you, and I don't ask you to respond today, I know you guys think about this issue on every day, literally you're trying to figure out what's the best policy, and what we really need is, okay, if you're going to change the nature of the Border Patrol where they can handle these types of situations better because again the population they're dealing with has changed in its character in a relatively brief amount of time and we're not getting single males from Mexico now. We're getting family units and unaccompanied minors.

You know, cartels, which used to be primarily engaged in drug trafficking, are now beyond human trafficking. I mean, this is not necessarily—but this is slowly facilitating illegal immigration.

So what do you need differently that you didn't have before and as appropriators, we always ask that, and how much will that cost us? So any thoughts you guys have on that would be gratefully received either here or at a later point.

And then the second thing is this, you know, what are—I think part of the conflict here between the parties is a sense, okay, is this open borders, anybody can come that wants to come and have to be received and give them resources, or, you know, what do we really do in terms of cases where, you know, people are legitimately—they're coming for economic opportunities as opposed to asylum?

It's that appropriate legal balance, which, you know, we have not been able as a Congress under either Democratic or Republican control and with either a Democratic or Republican Administration to really come up with something that we could get through anyway.

That becomes the second problem. What's the appropriate legal framework that we have to have to deal with these crises?

I guess the final point I would make, if we don't have a system, these things are going to just inflame public opinion when they happen. There has to be some agreed-upon system because they turn into political issues whether people meant them to or not. They simply do, having watched this twice, and therefore we need some sort of bipartisan policy.

It assures the American people, okay, when something like this happens, we have a plan that we've agreed upon and vetted and put into law that, okay, and this is how we're going to handle it. This is what we're going to do. So again I do think a lot of this has been reinventing the wheel and there have been some policy initiatives I certainly didn't agree with and the child separation policy I think has been an enormous mistake and I think has poisoned the debate and the discussion a great deal, you know, again but I don't blame anybody for being against that. I was against that and said so at the time. You just don't do it.

Then, finally, I guess I should say this last thing I would just say this whole knotty issue of who you're traveling with, you know, it's pretty easy if it's a parent or legal guardian. It really gets murky pretty fast after that, particularly if we have some reason to believe that, you know, a child may or may not be telling the truth in the sense they may feel intimidated into not telling the truth and again a lot of these, they're not young children. They are adolescents for the most part, they're teenagers, but they're certainly still susceptible to manipulation and intimidation in traveling with an adult and they've undoubtedly been told, okay, this is what you say when we get to this point.

There's got to be some direction we can give the Border Patrol person who is the first encounter. This is your sequencing. This is what—if it's this, do this. If it's this, do this. If it's this, do this, and then you've got to have it corrected pretty quickly within—because I agree very much with your point. I don't know that—I don't want these folks making that final decision. I don't think they want to make this final decision. They would love—okay. Let's facilitate this into an environment and with an appropriate set of childcare experts and what have you that could then make that decision. Just give us a place to move these children where they can get appropriate care and people other than just us that are enforcing law on the border are making the final decision and disposition about where the child goes.

Just for what it's worth, those are my thoughts.

Ms. HUANG. Thank you so much for those observations. I think there's a lot to respond to and will definitely try to provide you with some additional information.

MSC is monitoring the refugee crisis not just here in the Americas, in our country and in the Americas, we're actually monitoring it globally, and today there are more than 70 million displaced peo-

ple around the world, which is just an extraordinary number, nearly 26 million who've been identified as refugees, and that's not counting the asylum-seekers. Those are people who've been identified by the UN agency.

So you're right to anticipate that this is not the last surge, the last crisis, the last influx that we will have. We will continue to see more of this because what is driving people to make those moves is not singular, it's not a one-time thing, and it is larger patterns of violence, of civil conflict, of environmental degradation, of famine, things that are clearly causing different people to feel that they need to leave.

I think it is clear that we're not seeing the same economic imperatives of migration patterns now. We're seeing something very, very different, and the response therefore has to be very different. It's no longer about having a legal framework that takes into account economic priorities. It's about having a legal framework that recognizes our obligations to asylum-seekers and to protecting people who are so vulnerable and seeking refuge. That's a different framework.

Part of the problem is we've struggled with how to shift our policies from anticipating people who might be coming seeking work to people who are fleeing and looking for a safe haven.

So it's not an easy thing to switch on and off. It's something that we have to do collectively, but it's very clear that that is the future direction for all of us and that we have to be doing a better job.

I just wanted to note that on the notion of determining whether a child is traveling with an appropriate caregiver, for so many of the people who are fleeing now as part of this pattern, children have been left behind by parents. Parents may have come in the past seeking economic opportunity. The people bringing them now are often not the parent and so it's a recognition again of what this crisis is, the reason that they're traveling with non-parents and many of them don't have a legal guardian because that's not even plausible from some of those countries, is because of the circumstances that are driving it, and I think being responsive to that and thinking through policies that would recognize those facts and help create the appropriate setting is the most ideal.

But I think we're all looking for the same thing. If we can reunify families as quickly, as safely as possible, that is always in the best interests of the child, and I know that's been a driver for this committee. So thanks.

Ms. VIGNARAJAH. All excellent questions, so I'll try to very quickly respond in turn.

On the broader point, you know, I, of course, realize that it's easy to say, well, we should fund X, Y, and Z, but your responsibility is to figure out how do we find funding for it, and that is where—

Mr. COLE. That's actually now the Chair's. [Laughter.]

Ms. DELAURO. A willing Chair.

Ms. VIGNARAJAH. And I have full faith she will be able to do so.

But that is where, you know, obviously we've talked a little bit about our cost structure versus the influx facility cost structure, but even when you look at detention facilities versus alternatives to detention, you are literally talking about something around 350 versus \$15.

When we've shown that it is better for the family, better for the children, 99.7 to 99.8 percent compliance in terms of showing up for an ICE hearing, an ICE meeting, or your immigration court hearing, and so our point is that we can find the cost savings that will pay for all of this.

But part of it is making the sound investments now so that we don't have to all of a sudden, you know, in a rush stand something up, like Homestead, and I think that's where, you know, for me, it's about looking at the fact that, as you said, we had some notice. Obviously it wasn't like this happened over a two-year time span, but we did have some notice.

If you look at January, we knew that we had facilities for 3,000 members of families. We received 28,000 members of families and that to me was something that we saw even last year and I just don't think that we prioritized making sure that we had facilities responsive to the urgent needs of children and instead we implemented more of a militarized response which we know, of course, costs, you know, a lot more.

I think what I would say is that in terms of the planning, we do have to be a bit creative when we face these situations that, you know, we didn't plan for. For LRIS, what we've done in terms of our border work is that we've really taken a leadership role in Arizona as well as in New Mexico. That has been based on the churches who have stood up basically, you know, pop-up shelters, but we can do that in the context of providing the scale of beds we need, in the sense that we've got congregated care that can no longer be providing care for domestic children.

There are partners like us who have the expertise in terms of how to address children who are coming from other countries. It is why we've been incredibly aggressive in part because when I visited Homestead, I said to my team, look, we can stand here and criticize from the sidelines or we can actually find a way to be a part of the solution which is why in short order we will actually be proposing that we have 600 placements for children in our facilities because we know that we do need to scale up and be creative.

But the other piece of it is that, you know, when you look at even the infrastructure we have for refugees, so some of our work is refugee resettlement, because we operated just a couple years ago at a time where the resettlement agencies were able to bring in and help a 110,000 refugees, now we're at 30,000. If we can be creative in identifying opportunities like that and repurposing them, I do think there are ways in which even today we would not need temporary influx facilities.

On the question of the legal framework, look, I appreciate your comments in terms of taking this out of the political pinball machine because it's true. I don't think anyone is really advocating for open borders and until recent rhetoric, I don't think anyone was advocating for closed borders. That was not what America stood for, and I say that as someone who fled a civil war when I was nine months old. My parents brought me here from Sri Lanka.

But I can tell you that coming from a country divided along religious lines and being able to come to a country where there was a response of people welcoming us, who were Lutheran and Catho-

lic and Jewish and Muslim, that has always been America and that, I think, is—you know, there is great area.

Of course we need comprehensive immigration reform, but in terms of the policies we have in place, they are responsive even to the climate that we're dealing with right now. When you look at the legal right to asylum, 88 percent of people who are coming across the border are meeting that initial threshold of a credible fear. We know that they're not coming here with whimsical claims.

In terms of, you know, this metering policy that has been recently instituted, when you think about the deaths that we have seen in recent days, and I say this as the mother of a two-year-old, when, you know, Valeria and her father died crossing the Rio Grande, it wasn't because you had an ill-suited father who made a decision on whim. It was because he was told when he went to a port of entry that he couldn't come across because the door wasn't open at that time and when he realized that he would have to remain in a foreign country that is incredibly dangerous and that would have to be for at least 20 to 30 days, he took what is an act of desperation.

I think that that's where, you know, when I see the progressive sequencing of that golden door closing, first with the metering, then now with the interim final rule, again this is a strategy where we have a lot of the legal safeguards we need in place, meaning that right now under kind of our border control, if you have a firm offer of resettlement, you're not allowed to claim asylum here in the U.S., and likewise we can establish third party arrangements with other countries. We do it with Canada, but the reason why we don't do it with Mexico or Guatemala is, first, it doesn't meet the threshold of being a safe country and, second, there hasn't been any undertaking of does the legal system exist that would actually be able to offer asylum?

Finally, you have to still establish a negotiated agreement. The fact that the Administration pursued agreements and ultimately was not able to sign on the dotted line with Guatemala and Mexico, you can't announce an interim final rule. It's not just not legal and not within the framework that Congress smartly articulated, there's also no way to actually put it in place because you have countries that have been unwilling to actually take on that responsibility and so that's where I just think that there are opportunities to have bipartisan conversations because I would tell you we operate in 39 states, some of the most red and some of the most blue, and there is agreement. There is a way for us to have a workable system in place.

Ms. DELAURO. I honestly wish we had the entire subcommittee on both sides of the aisle to be able to listen to you.

I think one of the things that comes to my mind when I think about this is that if you start from the premise that immigration and immigrants are bad people, are trying to game a system, are trying to enter a country, you know, your word, as a whimsical reason, and that the tone that is set on the whole immigrant experience is so—in my view, I will use the word “polluted.”

You know, I am the daughter of an immigrant family. My father came in 1913 and the immigrant experience oftentimes gets romanticized in our country. It has forever been a very difficult experi-

ence and sometimes we lose track of the fact that we did have a government who said people could come from—first, when they came, it was whether or not at Ellis Island if you were physically all right, we embraced you, we embraced you.

Then we went through a period of time when we didn't want people from Southern Italy. We didn't want people from Eastern European countries. We began to sift out who it was that we wanted to be here and we can go through the history of immigration policy here, but we are at a time and I just say to you, Tom, you cannot have the whole experience for people or denigrate people who, for one reason or another, whether they were or now or in the past coming for economic reasons, they did. Why did my forebears come? They came for economic reasons, you know.

I understand my grandmother cried when she came because it was so beautiful in Amalfi, Italy, and it wasn't quite as beautiful in the United States of America or they found that the roads were not paved with gold but that they were going to have to pave the roads. They came with a hope and so forth and people have that same hope and drive and, quite frankly, Tom, we do not have an environment and that's not everyone. That's not everyone.

But there are those who want to just characterize this experience and characterize the people who are coming, some out of desperation because we know that's the fact and violence, etcetera, and trying to escape the violence, but that is a bad thing and that's not something that is acceptable any longer in our country and that we are going to have a militarized response to this. That sets a tone.

It sets a tone, and I think it's incumbent upon us to reverse that tone, and when someone can say that the border separation policy was understandably knowing that if you took a child from a parent, that that was going to create such heartbreak, that that would deter you from coming, that was at the base of that policy. That's what we are trying to say is wrong and that that has to be corrected and if that is corrected, then we maybe can look at the way we are dealing with people in an unmilitarized way and in a way that says we have nurses and pediatricians and the kind of case-work people that are needed in order to make this process work or that—you know, our own law says you can seek asylum anywhere in this country. You can come from anywhere to seek asylum, but we have so—excuse me—bastardized that view and so what we've done with it as to create a problem of metering or other pieces of legislation that turned this into such a tragic set of circumstances for people.

You know, it is about resources. What are the kinds of legal services that we are providing for people? You know, we found out at Homestead, because they're 13-to-17-year-old kids there, they read the Know Your Rights. I have a 15-year-old granddaughter, a 14-year-old granddaughter, a 12-year-old granddaughter and grandson. You take a manual and read them their rights. They don't know what they're listening to. Who is there to provide legal counsel for people to represent their interests? What are we doing about a child advocate program, of expanding a child advocate program?

What are we doing about the services that we provide for post-release, you know, for these kids or for their families? That is the road that we ought to be investing in instead of saying we need

5,000 more beds. We wouldn't need the beds if we are—and, you know, we had a case management system, Tom. We did. It was working. 90 percent of the people were showing up for the hearings. 2016 that was ended.

Let's think about—you all, not us. We are political people. We do. We come from a different perspective, different spectrum, et cetera. You can be of such critical importance to influence in the kind of public policy that we can engage in and if we can't agree, you know, we have a lot of very reasonable people on both sides of the aisle, that I think if we had the kind of counsel that you all could provide that we can't initiate legislation that could help to make a difference.

I want to make a speech. There are lots of questions, but I think we're at the point of no longer any questions.

Mr. COLE. Can I add one word, Madam Chair?

Ms. DELAURO. You can add any point, Mr. Cole.

Mr. COLE. We will get an exact count of the reasonable people we have on the budget vote later this week.

Ms. DELAURO. Hear hear. Hear hear. But you know what I'm saying. We can come together to do this, but it starts with a vision. It starts with a philosophy. It starts with a value system that says this is what we believe the United States of America should be about. We believe in that. You do.

Thank you so much for staying as long as you did today and for your testimony but more than anything else for your determination, your commitment, and your compassion every single day. Thank you, thank you.

Let me formally close the hearing. Thank you.

[Answers to submitted questions follow:]

Committee on Appropriations
Labor, Health & Human Services, and Education Subcommittee
*Oversight of the Unaccompanied Children Program: Ensuring the
 Safety of Children in HHS Care (7.24.19)*

Questions for the Record

Submitted by Congresswoman Clark

***Questions for Assistant Secretary Johnson and Director Hayes: Sexual Assault in ORR
 Facilities***

Questions:

1. When a child reports an allegation of sexual assault, harassment, or abuse at Homestead, are the Miami-Dade police involved in investigating every single one of these allegations?

Response: Care providers must report sexual abuse, sexual harassment, or inappropriate sexual behavior that occur in ORR care immediately (meaning no later than four hours after learning of the allegation). Care providers must report allegations of sexual harassment and inappropriate sexual behavior according to state law.

Care providers report allegations of sexual abuse (as defined in 34 U.S.C. § 20341 and in ORR regulations at 45 C.F.R. § 411.6) to child protective services (CPS), the state licensing agency, HHS' Office of Inspector General (HHS/OIG) and the U.S. Department of Justice's Federal Bureau of Investigation (FBI). In the case of a sexual abuse allegation involving only minors, CPS may cross-report to local law enforcement. If an allegation involves an adult, ORR policy requires the care provider to notify local law enforcement. Law enforcement investigates according to state law.

2. When a child reports an allegation of sexual assault, harassment, or abuse at Homestead, is the Florida Department of Children and Families involved in investigating every single one of these allegations?

Response: CPS investigates allegations of sexual misconduct according to state child welfare laws and procedures.

3. How many times were the Miami-Dade police notified after a child reported an allegation of sexual assault, harassment, or abuse?

Response: As noted above, care providers must report any allegation of sexual abuse that involves an adult to local law enforcement. From FY 2016 to July 2018, seven allegations of sexual abuse involving Homestead staff were reported. Six of those allegations were reported to law enforcement. One case was not reported to law enforcement because the allegation involved a staff member making a sexual comment to a child. This allegation was reported to the FBI and HHS/OIG as possible “grooming.” Four of the six reported allegations were reported after the child was discharged from the Homestead Influx Care Facility (Homestead ICF), and therefore Miami-Dade police may not have been the law enforcement agency that received the report.

4. Have the Miami-Dade police ever been turned away by Homestead Security when arriving to investigate a call on sexual misconduct or abuse?

Response: ORR has been made aware of an allegation that security contractors at the Homestead ICF turned away Miami-Dade police, and is currently looking into the allegation. Homestead is required by regulation to cooperate with outside investigators. If Homestead contractors did turn away local law enforcement, ORR will take appropriate remedial action with Homestead.

5. During the hearing on July 24, 2019, Director Hayes committed to investigating the extent to which the State of Florida is involved in investigating sexual misconduct taking place at Homestead. On what date will Director Hayes release a report on this issue?

Response: Director Hayes committed to looking into allegations that the State of Florida was not permitted to enter the Homestead ICF to investigate allegations of sexual abuse. The Florida Department of Children and Families (DCF) has investigated allegations of sexual abuse at the Homestead ICF, as evidenced by detailed reports submitted by Homestead. ORR continues to work with Comprehensive Health Services (CHS), the ORR contractor on site, and the State of Florida to ensure that all allegations of sexual misconduct are appropriately reported and investigated.

6. During the hearing on July 24, 2019, Assistant Secretary Johnson stated that “we are going to be providing all the details and information on the assaults and questions about those [incidence of sexual misconduct in Office of Refugee Resettlement facilities].” Director Hayes then went on to say that the report would be released “by the end of July or early August.”
 - a. What date does the Administration for Children and Families intend to release the report?

Response: ORR’s Interim Final Rule on Standards to Prevent, Detect, and Respond to Sexual Abuse and Sexual Harassment Involving Unaccompanied Alien Children (IFR) requires care providers and ORR to regularly collect and report aggregated information about sexual abuse and sexual harassment allegations in order to detect patterns so that future incidents can be prevented. Care providers must provide this data from the previous calendar year to ORR no later than August 31. The IFR further provides that ORR use this data to write an annual report, which ORR then posts on its website. ORR will post the 2015/2016 and 2017 annual reports soon. ORR is currently reviewing the data collected for calendar year 2018.

b. What types of details will be included in the report?

Response: The report includes aggregate data about substantiated sexual misconduct allegations involving minors, staff, and non-staff adults. The data includes information about the gender of victims, who reported allegations, follow-up services provided for the victim, actions taken for the perpetrator, and sanctions imposed on the perpetrator.

c. Will the report discuss influx facilities or all Office of Refugee Resettlement facilities?

Response: As part of the data collection process, ORR requested information from care providers about substantiated (that is, investigated and found to have occurred) incidents of sexual abuse, sexual harassment, and inappropriate sexual behavior. ORR’s Interim Final Rule does not apply to secure care providers, which must follow DOJ’s National Standards to Prevent, Detect, and Respond to Prison Rape. Additionally, influx care facilities are exempt from the data collection requirement. However, ORR made efforts to collect data from all care providers, including secure and influx care facilities.

Care providers relied on dispositions or findings from their state CPS, state licensing entity, or local law enforcement to determine which incidents were substantiated. In some states (Arizona, Florida, Georgia, and Michigan), CPS or state licensing does not formally investigate or provide care providers with a disposition or finding for each allegation. Additionally, shelter programs in New York, and the influx facilities Fort Bliss and Holloman are unable to provide information about the disposition of each allegation. However, ORR care providers in these states are provided with information about whether sexual abuse allegations involving staff were substantiated.

- d. Will the Administration of Children and Families and the Office of Refugee Resettlement provide a briefing to members of the Labor, Health and Human Services, Education, and Related Agencies subcommittee on the findings of the report?

Response: ORR will be available to provide a briefing to members of the Labor, Health and Human Services, Education, and Related Agencies subcommittee on the findings of the report.

7. Please provide a detailed step-by-step explanation of what actions are taken by HHS and ORR when a child in any ORR facility reports an allegation of sexual assault, harassment, or abuse.

Response: ORR reviews every report of sexual abuse submitted by care provider facilities to ensure that care providers comply with ORR regulations and policies. Care providers must use multiple protection measures to ensure the safety and security of victims, including housing changes within a facility, transfers to a different facility, and emotional support services. ORR also reviews allegations to ensure that care providers respond appropriately to the allegations using child welfare principles.

In all cases of an allegation of sexual abuse care providers must:

- Report the allegation to ORR, state/local child protective services (CPS), state licensing, HHS' Office of the Inspector General, and the U.S. Department of Justice's FBI.
- Report allegations of sexual abuse that involve an adult to local law enforcement.
- Cooperate with any investigation of the allegation, including by CPS, licensing or law enforcement.
- Take immediate action to protect the victim and the safety of other children in the program (i.e., separating the victim from the perpetrator, increasing supervision, housing changes, and transfers).
- Provide follow-up services, including medical or mental health services.
- Make appropriate notifications to parents, legal guardians and sponsors, attorneys, and child advocates, if applicable.

If a sexual abuse allegation involves a staff member, the care provider is required to suspend the staff member from all duties that would provide the staff member with access to pending investigations regarding children. After investigation by an oversight entity, a care provider must take disciplinary action up to and including termination for violating ORR's or the care provider's sexual abuse-related policies and

procedures. Termination is the presumptive disciplinary sanction for staff who engaged in sexual abuse or sexual harassment.

8. Are there any outstanding allegations of sexual misconduct, harassment, or abuse that have not been resolved? If so, how many and what is the status of each of these investigations?

Response: There are no ongoing investigations of the seven allegations of sexual abuse involving Homestead staff from FY 2016 through July 2018. Of these seven allegations, four allegations were administratively closed by state agencies after an initial review; two allegations were investigated and determined to be unfounded; and one was investigated and determined to be substantiated. With respect to the one substantiated allegation, the staff member was convicted of attempting to coerce and entice an unaccompanied alien minor to engage in illicit sexual activity. She received 10 years imprisonment and 50 years of supervised release.

Question for Director Hayes: Teenagers turning 18 in ORR Custody

Question:

1. When teenagers turn 18 in the care of the Office of Refugee Resettlement, are these individuals handcuffed and escorted into the custody of Immigration and Customs Enforcement (ICE)?

Response: UAC who “age out” of ORR care are referred to DHS custody, because by statute ORR can care only for minors. ORR defers to ICE to answer any questions regarding handcuffs and its standard practices when taking custody of former UACs who turn 18 while in ORR care. ORR does not provide handcuffs to ICE or any other law enforcement authority.

Committee on Appropriations
Labor, Health & Human Services, and Education Subcommittee
*Oversight of the Unaccompanied Children Program: Ensuring the
 Safety of Children in HHS Care (7.24.19)*

Questions for the Record

Submitted by Chair DeLauro

Additional Capacity

ORR testimony indicates you are pursuing a network of 20,000 State licensed beds. At its highest capacity, ORR had 15,000 children in care – and the main reason ORR had so many children in care was because of the excessively long stays in care: because of the MOA, the fingerprinting requirements and the data sharing with DHS resulted in discharge rates less than 1.0.

Question: What were the discharge rates in the months leading up to when ORR had 15,000 children in its care?

Response: ORR has never had 15,000 UAC in its care at any one time. The largest census ORR has ever taken was 14,775 children in December of 2018. The following chart highlights the discharge rates for each month leading up to ORR’s census of 14,775. In June 2018, ORR’s highest total number of children was 11,887, with a discharge rate as follows:

Month	Discharge Rate
FY18	
June 2018	1.2
July 2018	1.2
August 2018	0.7
September 2018	0.8
FY19	
October 2018	1.0
November 2018	0.9
December 2018	1.5

ORR has made several policy revisions pursuant to a series of operational directives that have accelerated the safe release of children to sponsors. These changes contributed to ORR achieving a discharge rate of 2.3 percent in June of 2019.

Question: What data has ORR used to justify needing long-term capacity of 20,000 permanent beds? Has this been based on CBP projection data?

Response: ORR projected needing up to 20,000 beds based on a series of data points and trends it tracks to determine its capacity needs. The data points include levels of placements, referrals, and discharges over previous months and years. However, ORR's long-term capacity needs are always subject to change as there is no definitive method to gauge the amount of future UAC that will come into ORR care. Based on the most recent data, ORR is evaluating its projected bed needs and does not think 20,000 beds are justified at this time.

Question: What is the target operational capacity ORR wants to maintain for its network of State-licensed shelters?

Response: ORR targets for a network-wide operational capacity (defined as the total number of available state licensed shelter and transitional foster care beds) of no more than 85 percent.

Discharge Rates

Question: What efforts is ORR putting into focusing on higher discharge rates? What would ORR need in order to have a discharge rate higher than 2.0?

Response: ORR seeks to release UACs to appropriate sponsors as quickly and safely as possible. To encourage higher discharge rates, ORR is focusing efforts on recruiting and training adequate staff at our grantees, contractors, and federal level to facilitate timely release of UAC from ORR custody. However, the focus of discharge rate is not exclusively on releases to sponsors. ORR achieved a discharge rate of 2.1 percent in May 2019, and 2.3 percent in June 2019. A Discharge Rate Improvement plan required by P.L. 116-26 provided additional details on ORR's efforts and plans to continue to have a high discharge rate. Please note though that a high discharge rate is not the only benchmark by which success is driven, as there are many factors that go into individual cases.

Carrizo Springs

This Committee needs to know more about the plans for Carrizo Springs. We need to know what it would take for this facility to work towards State-licensure or what can be done for this facility to meet the same requirements under Flores as licensed facilities in Texas.

Question: How long is the lease ORR entered into with the Carrizo Springs facility?

Response: The lease is for three (3) years with two (2) option years.

Question: Is your intention to keep Carrizo Springs vacant while it is not operating as an influx shelter or will it be used in some other way?

Response: Carrizo Springs is not activated at this time, it is on reserve status. Reserve status means the site is closed, but can be activated and ready for UAC in a short timeframe.

Question: What efforts or investments can ORR make to improve the infrastructure of Carrizo Springs so that it could be operated as a State-licensed shelter?

Response: Carrizo Springs meets key health and safety standards, and children who reside at this facility would generally receive the same level of care and services to UAC as a state-licensed facility. ORR is examining what infrastructure improvements or modifications would be necessary to come in line with state licensing requirements.

Mental Health Resources

Last year, this Committee included an additional \$4 million in funding through SAMSHA to help unaccompanied children suffering from the trauma of family separation.

Question: How is ACF coordinating with SAMHSA to connect children in ORR care to services through the National Child Traumatic Stress Network?

Response: ORR collaborated with the National Child Traumatic Stress Network (NCTSN) in developing a webinar series on childhood trauma, which is currently available within NCTSN's Learning Center for Child and Adolescent Trauma. ORR informed care provider programs of this e-learning series so the webinars can be integrated into the programs' training curricula.

Additionally, ORR met with NCTSN grantees and connected them with ORR's post-release case management service providers, so that released children who are in need of continued mental health care are referred to NCTSN grantees for ongoing care. NCTSN grantees are also working with ORR in identifying ORR-funded care provider programs that are within the catchment area of NCTSN grantees, to train care provider clinical staff on evidenced-based trauma-informed care.

Young Children

Question: How many children under the age of 3 are currently in ORR custody? Can you provide the Subcommittee with a breakout by age and length of time in your care and whether they are housed in facility/group settings or in single-family homes?

Response: Please see the following chart broken down by age and average length of care. ORR does not track, through its Portal, the type of setting (individual foster home vs group home) a UAC is sheltered in. With respect to Long-Term Foster Care, grantee programs may have a bed capacity that mixes both single family homes and congregate care.

UACs ages 3 and under In Care as of 9/09/19*								
Age	ORR Shelter		Transitional Foster Care		Long Term Foster Care		Total # of UACs	Total Average LOC
	# of UACs	Average LOC	# of UACs	Average LOC	# of UACs	Average LOC		
0	71	50	19	91	3	129	93	61
1	31	83	28	93	5	439	64	115
2	18	99	17	73	1	885	36	109
3	11	72	22	92	2	710	35	121
Total	131	66	86	88	11	444	228	93

*Please note that this data is unreconciled

Question: What type of legal services are being offered to children under the age of 5 in ORR's care?

Response: ORR does not prescribe how its funded legal services providers conduct legal screenings or give Know Your Rights (KYR) presentations to UAC. However, providers must assess very young UAC for their understanding of what is being said and adjust the legal screenings and KYR presentations accordingly, to accommodate for the age of the child. One example is when Vera, an ORR-funded legal services provider, created a pamphlet that uses pictures to try to explain the immigration process.

Question: Does ORR plan to increase the number of stable family foster placements to accommodate every child under age 3 in your care? If so, how will you do that? If not, why are you not going in that direction?

Response: ORR seeks funding applications from potential grantees to meet the needs of UACs with special needs, including infants and toddlers, and will be reviewing applicants from a recently posted Funding Opportunity Announcement (FOA) that closed in November calling for transitional foster care applicants.

Question: Have you worked with infant and early childhood mental health experts to understand and take steps to address the effects of the almost unspeakable trauma they have experienced?

Response: ORR is committed to improving and strengthening mental and behavioral health services and delivery to UAC while they are in the care and custody of ORR, and provides trauma-informed care to all UAC in care. In April 2019, ORR hired a board certified child and adolescent psychiatrist to develop a comprehensive UAC mental and behavioral health service delivery program. To that end, ORR meets monthly with a group of psychiatrists and a psychologist, some of whom are nationally or internationally known in the field of infant and child mental health and infant and child trauma. This group has been instrumental in guiding ORR on when and how to screen for trauma in our vulnerable child and teen populations.

Additionally, as mentioned above, ORR collaborates with the National Child Traumatic Stress Network (NCTSN) so that children with ongoing mental health needs who have been released to sponsor families can be referred to NCTSN grantees for continued care. To aid in this effort, ORR distributed NCTSN grant awardee information to the American Academy of Pediatrics (AAP) to further disseminate mental health resources for released UAC. Finally, ORR continues to discuss UAC health care with AAP immigrant child health clinicians to better medical and mental health care service delivery for UAC.

Medications

Question: If a child arrives with medication for a known health condition, is it ORR policy to confiscate the medication that children arrive with?

Response: If a child arrives to an ORR-funded care provider program with medication for a known health condition, the program staff will review all medical documentation transferred with the child and ensure that medication is properly and safely administered. ORR does not allow self-administration of medications by children outside the presence of care provider program staff member.

ORR-funded care providers must have policies and procedures based on State or local laws and regulations to ensure the safe, discreet, and confidential provision of prescription and nonprescription medications to UAC, secure storage of medications, and controlled administration and disposal of all drugs.

A licensed health care provider (a nurse, physician, physician's assistance, nurse practitioner) must write or verbally order all nonprescription medications. Verbal orders must be documented in the child's file.

ORR's policy on medication administration can be found in the ORR Policy Guide Section 3.4.4 (<https://www.acf.hhs.gov/orr/resource/children-entering-the-united-states-unaccompanied-section-3#3.4.4>).

Question: What is the policy for children arriving with medication specifically at the Homestead facility?

Response: Temporary influx care facilities, such as Homestead, are required to adhere to ORR medical services standards, including policies and procedures involving medication administration, to the same extent ORR requires at licensed facilities.

Legal Services

Question: How many ORR facilities have opened in the last 3 months where there is no legal service provider under contract to provide children with critical and necessary legal services required by law, such as in-person know-your-rights presentations and legal screenings?

Response:

The *Flores* Settlement Agreement (*FSA*) requires that ORR provide legal service information regarding the availability of free legal assistance, the right to be represented by counsel at no expense to the government, the right to a deportation or exclusion hearing before an immigration judge, the right to apply for political asylum or to request voluntary departure in lieu of deportation. ORR provides this information to UAC in the form of Know Your Rights presentations but they are not required to be in-person, although it is ORR's preference and practice that they are in person whenever practicable. Legal screenings are not required by law, but are a service ORR provides through the legal services contract.

ORR's legal service provider Vera has sufficient funding to provide services at all ORR operational shelters; HHS had not authorized Vera to re-program funds to support two shelters which opened in Summer 2019. However, Vera worked with its local providers to ensure Know Your Rights presentations and legal screenings were provided at these locations on a pro bono basis upon their opening. As of September 12, 2019, HHS authorized Vera to re-program funds to provide these services at all operational shelters.

Question: What is ORR doing to modify the contract with the legal services provider to see that as new facilities come online, legal services are provided on Day 1 – and throughout a child's care with ORR?

Response: When ORR finalizes grant awards to open a new shelter, it works with the legal service provider to modify the existing contract as quickly as possible if necessary to ensure timely provision of services. ORR works with the HHS contracting office to make appropriate adjustments to legal services contracts. . Timing contract modifications to match up with opening new beds is difficult because each follow separate processes, and involve different HHS entities. Additionally, variables with a particular facilities ability to operate, obtain a license, and hire staff can make determining precisely when a facility will be able to open accept placement

inexact. Additionally, some facilities operating in areas that currently have no coverage with a current local legal service provider, require the prime legal service contractor time to recruit and engage a new local legal service provider to cover the new facility. The process for recruiting local legal service providers is the responsibility of the prime legal service contractor, and follows their sub-contracting and staff hiring/recruitment protocols.

Question: With supplemental funding, how will ORR work to ensure children have the representation that is required by law?

Response: ORR uses the supplemental appropriation to fund expansion of the legal services contracts to accommodate influx capacity and the new licensed capacity from the funding opportunity announcement posted in March 2019, and to exercise the next option period to continue legal services into FY 2020.

Committee on Appropriations
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*Oversight of the Unaccompanied Children Program: Ensuring the
Safety of Children in HHS Care (7.24.19)*

Questions for the Record

Submitted by Congresswoman Lee

ORR to ICE

Mr. Hayes, during your testimony, you mentioned a lot of the services that are offered to minors, meaning youth between the ages of 13 – 17 years of age. While I was at Homestead, I also noticed that there was not clear guidance on what happens when a child turns 18.

Question: Are the children shackled on their 18th birthday? To what extent is ORR communicating with ICE or the FBI on the recently released adults? What are your benchmarks for discharge, and could you please be specific?

Response: Aliens who “age out” of ORR care are transferred to DHS custody, because by statute ORR can care only for minors. See 6 U.S.C. 279(g)(2). ORR defers to ICE to answer any questions regarding handcuffs and its standard practices when taking custody of former UACs who turn 18 while in ORR care. ORR does not provide ICE or any other law enforcement authority with shackles.

If an alien turns 18 and ICE assumes custody, ORR does not communicate with ICE regarding their detention, nor does ORR communicate with the FBI regarding any adult in ICE custody.

ORR may discharge individuals from its care in a variety of circumstances and for many different reasons. The vast majority of children are released to a sponsor. ORR begins the process of finding family members and others who may be qualified to sponsor an unaccompanied alien child as soon as the child enters ORR’s care. Parents, relatives, or close family friends may apply to have the child released to their care, and these potential sponsors go through a comprehensive application and screening process before ORR will release a child into their care. The ORR Federal Field Specialist determines if the release to the sponsor is safe, the sponsor can care for the health and well-being of the child, and the sponsor understands that the child is to appear for all immigration proceedings.

In other circumstances, a minor could be discharged from ORR's care if their immigration status changes, such as if they gain immigration relief, voluntarily depart back to their home country, or are ordered removed from United States. In each of these circumstances, the immigration court makes the decision regarding the minor's status, and ORR has no input or control over these decisions. In limited circumstances, children with certain types of immigration status may be eligible for release into the Unaccompanied Refugee Minors (URM) Program. Placement in the URM Program is limited by type of immigration status and the availability of appropriate placement options. By law, the minor in these circumstances no longer qualify for ORR care and would be discharged.

In some cases, a minor may age out of ORR care before they can be released to a sponsor or their immigration status changes. In this case, ORR notifies DHS 24 hours before the minor turns 18. ORR will not release children on their own recognizance under any circumstances.

EDUCATION

During the Homestead trip, we toured educational facilities that were composed of tents. This was not very ideal for the educational development of these individuals. However, what was more concerning was the amount of noise that could be heard in the tents.

Question: How can children learn in this environment? What is being done to ensure that these children can learn in an adequate environment?

Response: As of August 3, 2019, there are no children at Homestead.

Prior to transferring children out of Homestead, there were 52 classrooms housed in multiple education tents on both sides of the campus. All structures were climate controlled, with power and lighting. ORR and the staff at Homestead ensured children learned in an adequate environment by hiring qualified lead staff who managed the provision of services and developed an educational curriculum to meet the needs of UAC at Homestead. Homestead's Director of Education has over 26 years of curriculum-writing experience; has been an educator and assistant principal; and is currently a doctoral student at the University of the Incarnate Word, and the Superintendent Cohort at the University of Texas at San Antonio. Homestead education staff is created/updated bilingual project-based lessons to implement didactic learning and other innovative techniques to continually improve education services to children.

Education services at Homestead met the requirements of all ORR policies, procedures, and applicable federal authorities, including the Flores Settlement Agreement. All children were provided an educational assessment and educational plan; classes were provided in a structured classroom setting Monday-Friday (6 hours minimum); the education curriculum concentrated primarily on the development of basic academic competencies and secondarily on English

Language Training; and basic academic areas included Science, Social Studies, Math, Reading, Writing, and Physical Education.

WEDNESDAY, SEPTEMBER 18, 2019.

**MENTAL HEALTH NEEDS OF CHILDREN IN HHS
CUSTODY**

WITNESSES

**JONATHAN HAYES, DIRECTOR, OFFICE OF REFUGEE RESETTLEMENT,
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

JONATHAN WHITE, COMMANDER, PUBLIC HEALTH SERVICE COMMISSIONED CORPS, DEPARTMENT OF HEALTH AND HUMAN SERVICES

ANN MAXWELL, ASSISTANT INSPECTOR GENERAL, OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Ms. DELAURO. The subcommittee will come to order.

Good morning to all and welcome to the Labor, HHS, and Education Appropriations Subcommittee.

We are here today for another oversight hearing, and this time with administration officials and members of the Department's Office of Inspector General, to discuss the recently released report on the mental health needs of children in the care of the Department of Health and Human Services Unaccompanied Children Program.

I want to thank our witnesses for being here today: Ann Maxwell, Assistant Inspector General, Office of the Inspector General, the Department of Health and Human Services; Jonathan Hayes, who is the Director of the Office of Refugee Resettlement, the Department of Health and Human Services; and Jonathan White, Commander, Public Health Service Commissioned Corps, Department of Health and Human Services.

This hearing is really part of our oversight responsibility, which we take very, very seriously. We must. Considerable taxpayer resources are at stake, and something even more precious is at stake, and that is the mental and the physical well-being of children.

That is why the Office of the Inspector General's new report was so alarming. It confirms our worst fears, that intentional policy choices by this administration created what I would call a mental health crisis, which the Office of the Inspector General said that Health and Human Services and the Office of Refugee Resettlement failed to address. It is a crisis of deliberate government-sanctioned child abuse. We must stop the trauma inflicted on these children. So I believe the administration must quickly implement the OIG's proposed recommendations, which are included in the report.

The Administration for Children and Families has concurred with each of the recommendations, but words alone are not enough. The gaps created a mental health crisis as children are still dealing with the effects.

As Ms. Maxwell summarized on page 8 in her testimony, and I quote: "Policy changes in 2018 exacerbated existing challenges, as they resulted in 1) a rapid increase in the number of children sepa-

rated from their parents after entering the United States, many of whom were younger, and 2) longer stays in ORR custody for children,” end quote.

Those policy changes in 2018 were the administration’s zero tolerance family separation policy, which ripped children from their parents, and the administration’s grossly intentional changes to fingerprinting and screening requirements that ground discharge to a halt. As a result, a child’s average length of stay in government custody nearly tripled, from 35 days to 93 days.

The numbers have improved since the administration began implementing its four operational directives in December to reverse their changes to the screening process. I will note that those changes followed a consistent drumbeat for accountability from the subcommittee. Now we need to see the agency’s plan to improve the discharge process, so that we are able to get children in and out of ORR’s care as safely and as quickly as possible so they do not experience toxic stress and mental trauma. We do not only need a plan for bed capacity.

And, as I understand it, the onus with respect to discharge is on the grantees, and that is the contractor is responsible for the discharge consistent with policies, ORR policies and regulations, but the contractor is responsible.

So ORR must then have policies in place that get children in and out of the facility as quickly as possible, because when Homestead, which is an influx facility, is charging \$750 per night per child, the motivation to move these kids may not be as strong as it needs to be.

There must be change, because, as the OIG concluded, children have been suffering because of these intentional policy choices. Ms. Maxwell wrote in her testimony on page 9, again, I quote: “Children who experienced longer facility stays exhibited higher levels of defiance, hopelessness, and frustration, along with more instances of self-harm and suicidal ideation,” end quote. Also in her testimony on page 8: “Separated children exhibited more fear, feelings of abandonment and post-traumatic stress disorder than did children who were not separated.” And the OIG’s report on page 10 also described how some separated children expressed acute grief that caused them to cry inconsolably.

In another story, the OIG’s report shared that, quote: A 7- or 8-year-old boy who was separated from his father without any explanation as to why the separation occurred. The child was under the delusion that his father had been killed and believed that he would also be killed. This child ultimately required emergency psychiatric care to address his mental health distress. This is terrible. And then the administration failed to fully or adequately treat it.

As the OIG report spotlighted in its executive summary: Quote: Facilities struggle to address the mental health needs of children who had experienced intense trauma and had difficulty accessing specialized treatment for children who needed it. Overwhelmed by the deluge, clinicians reported caseloads more than doubled what they should have been. And unprepared for the younger children, those mental health providers who were available were primarily prepared to serve teenagers, not the mental and the social needs

of preschoolers, who cannot communicate their backgrounds, their needs, or even their pain.

So, as I read the OIG's report and testimony, the administration's intentional policies traumatized youngsters who then did not receive the proper care they needed. And I will say it very honestly, I believe it is twisted and it is shameful.

Let me add that we do not know the mental state of the children who were separated in 2017. That is a matter that is still in the courts. And understand, we only know about the 2017 children because of the Office of the Inspector General and the ACLU.

And it is really very interesting to me as to at the time of July 2018, who made the decision to certify a list that was inaccurate? It was 2018, not what happened in 2017. What was the role? I don't know, Mr. Hayes, about your role. What factors went into making that decision?

Now, we can also assume that the trauma of these children mirrors that of the children that the OIG identified in this report. It should add to the urgency we feel to stop the trauma. ORR is a child welfare agency, and we must be ensuring it is upholding its mission, which brings me to the OIG's recommendation.

One recommendation from OIG is that ORR should take all the reasonable steps to reduce the time that children remain in ORR's care. I wholeheartedly agree. In fact, I will reiterate what I have been saying to this administration for months: Rescind the memorandum of agreement between the Department of Homeland Security and the Department of Health and Human Services.

With respect to the agreement, the subcommittee has heard from outside witnesses and ORR grantees, who said it continues to scare away potential sponsors who otherwise want to take care of a child, but are too afraid to come forward. In fact, at our July hearing, Assistant Secretary Johnson agreed with the subcommittee that the memorandum of agreement should be rescinded.

Since there has not yet been any action, it would appear that the responsibility to rescind the MOA is in the hands of the White House, because if the administration wholeheartedly agrees with the OIG's recommendation here then the administration must rescind the memorandum of agreement immediately.

Another recommendation from the OIG is that ORR should identify and disseminate evidence-based approaches to addressing trauma. Again, I wholeheartedly agree. This subcommittee has repeatedly provided resources for the care of children in the appropriations bills that the House passed the last 2 years and in the emergency supplemental bill.

With respect to the 2019 appropriation, I want to say a thank you to Ranking Member Tom Cole, then Chairman Cole, for accepting, by voice vote, my amendment to provide funding for SAMHSA, the Substance Abuse and Mental Health Services Administration, through the National Child Traumatic Stress Network, in what was a total increase of \$10 million for the network, \$4 million of which was for these children. And I just say clearly today that we need more funding to the Stress Network to deal with this issue.

We are committed to ensuring ORR and HHS are upholding their mission to care for children, not to act as a tool of immigration enforcement, which is why we need to see the administration

quickly implement the necessary changes, including the OIG's recommendations.

Children did not just arrive at our border. They suffered by our hands and they are suffering still due to the long-term mental health trauma. That is not something that we can ignore or that we can sweep under the rug. We need to stop the pain and the suffering. Caring for the most vulnerable is the most sensitive of our duties as members of this body and as a people of this great Nation. There can be no greater sin than allowing ourselves to live by a lesser standard.

So, to close, I want to say a thank you to the OIG for this report, for your work. I look forward today to hearing more about it, hearing from the administration, and I hope to learn from HHS how you intend to take—to prevent the traumatization of youngsters as a result of—the way I characterize it—the administration's cruel and heartless immigration policies moving forward.

First, let me introduce my Republican colleague, the ranking member of the subcommittee, Congressman Tom Cole of Oklahoma, for any remarks that he would like to make.

Mr. COLE. Thank you very much, Madam Chairman. And I am going to depart from my prepared remarks for just a second, because I want to begin with four thank yous.

And the first one is to you. Your focus on this issue has been unrelenting and I think appropriate. And while we may disagree over this or that interpretation, the fact is you have kept this committee focused where it needed to be, on the welfare of these people, and you deserve all of our thanks. It is the right way to do oversight, and you have done it.

I want to thank the IG. You know, we have IGs because we—you know, my mom used to have a wonderful saying, you are friends with the people that tell you what you need to know, not what you want to hear and I think, Ms. Maxwell, you told us what we needed to know and not necessarily what we wanted to hear, but I think that is your job and you did it very well in this case and I appreciate it.

I also want to thank Director Hayes. I had the opportunity to travel to the border region with him over the August break, and I see a lot of effort to implement some of the changes and to be responsive to criticism and to correct the situation that we all agree.

And finally, to a much maligned Congress, I want to give a thanks to the Congress. It took us a little too long, but we finally gave the administration the resources it needed in the emergency supplemental. And it hasn't solved every problem, but I can tell you things are a lot better than they were 90 or 120 days ago, because Congress acted.

Again, it took us 6 weeks. We did the same thing for President Obama in 2003, but in the end it was a bipartisan action by Congress that provided the resources that began to let us address some of the problems that Ms. Maxwell has very appropriately and I think wisely pointed out. We still have a long way to go, but this was a promising start.

So, with that, Madam Chair, I want to welcome our witnesses for the subcommittee's third hearing on Unaccompanied Alien Chil-

dren Program. Today we are here to focus on the mental health needs of children in the care of the Department of Health and Human Services.

Before we begin, I want to focus a little on the history of this program over the past few years. In 2012, this program received an appropriation of \$169 million. This past year, the fiscal year 2019 appropriation, this committee provided more than \$1.3 billion. In just 7 years, the appropriation for this program has grown by more than 670 percent. So there certainly has been a focus on it here.

In 2012, the Department of Health and Human Services' Office of Refugee Resettlement had over 13,000 children referred to them by the Department of Homeland Security. In the current year, HHS has had over 60,000 children referred to them for care. By the end of the fiscal year, HHS will likely have cared for over 70,000 children, more children than in any prior year. Again, in just 7 years, an increase of 370 percent. Pretty staggering.

Both a Democratic and a Republican President have requested supplemental appropriations in the billions to support unanticipated arrivals of teenagers at our southern border. HHS now routinely cares for tens of thousands of children who travel thousands of miles, most coming from El Salvador, Guatemala and Honduras. Objectively, this is a crisis and one that needs a comprehensive bipartisan solution.

Federal law requires the Department of Homeland Security to transfer to HHS any unauthorized minor not accompanied by a parent or a legal guardian. This legal requirement means that when Customs and Border Protection or Immigration and Customs Enforcement apprehend a minor with an uncle, an aunt, a grandmother or grandfather or older brother or sister, the law defines that minor as unaccompanied and requires transfer of that child to HHS.

I understand there are many who believe these children should remain with the adult relative they are traveling with. However, that is not the law of the United States, and that is probably something we should look at.

I also want to address the topic of the zero tolerance policy implemented by the Department of Justice in 2018. The administration has made several attempts to stem the flow of migration happening to our southern border. The zero tolerance policy was clearly a mistake, and I am glad that the President quickly ended it, the implementation of it, but the consequences continue.

And while we may all disagree on the merits of such a policy, we can all agree HHS does not play a role in the establishment of immigration policy. HHS does not separate family. HHS does not separate children from their parents. HHS' responsibility is to care for children referred to them by DHS and to find suitable sponsors. And in that area, we have made considerable progress.

As I said, many of these children are coming to our borders through Mexico from Central America. It is no surprise that such an arduous, dangerous journey is traumatic. Many of the children left family members, poverty, and dangerous conditions to come here. Once apprehended by DHS, the children are turned over to HHS to begin the process of finding a sponsor.

For the short time the children are in HHS' care, they are provided with vaccinations, mental health screening, education and legal information. Referral to mental health services can be a part of that process.

The Office of Inspector General highlighted the challenges with meeting the mental health needs of the children in care. I want to point out that a significant portion of America, frankly, also faces the challenge of accessing mental health services. According to the Health Resources and Services Administration, 34 percent of the American population lives in a mental health professional shortage area. My own district alone has 22 such designated areas.

The challenges facing adequate access to mental health services is something many areas are having to deal with. I will just add parenthetically, when I was fortunate enough to be chairman of this committee and we had passed 21st Century Cures, there were a lot of mental health provisions in that.

And the Member most responsible, the former Member, Congressman Murphy, came to visit me and I said, look, you have got multiple things here. I can't fund them all. You know, they are going to give me a finite amount of money, I am not an authorizer, I got to live within a budget. Pick one or two things. And he hesitated for a minute. He said, the number one thing is we just need more mental healthcare professionals. Anything you can do otherwise, we are just competing back and forth for a very small pool of professionals. And so we need to invest more in creating literally the healthcare professional service corps that we need.

I also appreciate the desire for HHS' role in the care of these children to be expanded. However, given the unprecedented surge in the number of unaccompanied children crossing our southern border, HHS' primary focus should be the establishment of State-licensed and small facilities to care for children until placement with a sponsor is possible. And, again, I want to commend you, Mr. Hayes. You have done a lot more of that in the last 60 to 90 days, and that has been very helpful.

I know that my friends at HHS are doing their best that they can with a challenging situation. I want to commend them for the difficult work they are performing, and note that they are facing many of the same challenges faced by the prior administration. It is my hope that this committee will work with them in a bipartisan fashion to provide the resources needed to confront this urgent challenge.

With that, Madam Chair, I yield back my time.

Ms. DELAURO. Thank you very much, Congressman Cole.

I would like to yield to the ranking member of the full Appropriations Committee, Congressman Nita Lowey of New York.

Mr. COLE. She is the chairman.

The CHAIRWOMAN. What did you call me? You can call me anything you want.

Ms. DELAURO. I said the chair of the Appropriations Committee.

Mr. COLE. No, you said the ranking member.

Ms. DELAURO. Make no mistake, she is the chair.

The CHAIRWOMAN. I thank you, Madam Chair, my friend for a very long time. I want to thank Chair DeLauro and Ranking Member Cole for holding this hearing. And I thank Assistant Inspector

General Maxwell, Director Hayes, and Commander White for joining us today.

The fact that we are here again today is a clear example of how damaging and cruel the Trump administration's actions have been on the mental health of vulnerable children. This could have been largely avoided. Children belong with their parents.

Now, many of us have read this article in the New York Times, July 30, 2019, and it says: In testimony before Congress earlier this month, the Border Patrol's Chief of Law Enforcement Operations, Brian Hastings, said the agency has established that its agents may elect to separate a child from a parent if there is a determination that the parent or legal guardian poses a danger to the child, is otherwise unfit to care for the child, has a criminal history or a communicable disease, or is transferred to a detention setting for prosecution for a crime other than improper entry.

Seventy thousand children have been separated from their parents. I am going to say a few more words, but I find that astonishing. Two months ago, Chair DeLauro and several of our colleagues visited the Homestead influx facility. As I looked through the Inspector General's report on mental health needs of these children, it is clear we were not provided a full picture of ORR's challenges.

I am deeply concerned with the Inspector General's finding. Some of these include clinician shortage problems with access to external and specialized care and a lack of preparedness among clinicians to treat the level of trauma in these children.

What causes me even more concern is what we still don't know. Now, I just want to repeat this again, because—okay. I have just been corrected by my distinguished chair. Okay. I just want to conclude by saying, whether it was 70,000 or this number is wrong, I am not going to debate that now.

But my prime concern. No matter how clean Homestead was, no matter how many smiles were on the face of everybody, no matter how many books they were given to read, no matter how many toys they were given to play with, I just feel very, very strongly that children belong with their parents. And to leave it to the Border Patrol, who may elect to separate—a Border Patrol person, who may make the decision to separate a child from a parent, that Border Patrol person is making a decision as to whether the parent who brought the child here should be taking care of the child, better putting it in a facility away from their child.

This just doesn't make sense to me, and I cannot believe—and we met many of those children. I cannot believe that the parents of all of those children were unfit to take care of that child while they are waiting for a hearing. So let me just say it is clear, although we visited this facility and we saw some good things, but we saw many things that had to be corrected.

I just want to conclude again, because as good as your clinicians are, and they may be fine people doing the job, you can't tell me that thousands and thousands of children are better off in a facility, as clean and as smiling the people are, than being with their own parent. So that is really my point.

Ms. DELAURO. Thank you very, very much, Madam Chair.

We now are going to proceed to the opening remarks from Ann Maxwell, again, Assistant Inspector General, Office of the Inspector General of the Department of Health and Human Services; followed by Jonathan Hayes, Director of the Office of Refugee Resettlement, Department of Health and Human Services; and we are also joined by Commander Jonathan White, U.S. Public Health Service Commissioned Corps, who will be available to respond to questions.

Ms. Maxwell, welcome and thank you for being here today. Your full written testimony will be entered into the hearing record. You are now recognized for 5 minutes.

Ms. MAXWELL. Good morning, Chair DeLauro and Ranking Member Cole and other distinguished members of the subcommittee. Thank you for the opportunity to discuss OIG's ongoing oversight of the Unaccompanied Alien Children Program administered by the Office of Refugee Resettlement.

Today, I will be focusing on our findings regarding the challenges ORR-funded facilities face in addressing the mental health needs of children in care. These facilities serve migrant children who arrive in the U.S. on their own or who are separated from their parents by immigration officials. These children have often experienced intense trauma before coming into ORR care, which is why prompt mental health treatment is not only required by ORR, but is essential for a child's well-being.

My testimony reflects what we heard firsthand from facility staff across the country about the obstacles they face. We were told that there are a number of systemic challenges that make it difficult for staff to address the mental health needs of children. These include the ability to employ and support clinical staff.

Mental health clinicians reported heavy caseloads. They also asked for more training and support to treat traumatized children. In addition, staff face difficulties in accessing specialty care, such as psychologists and psychiatrists, to treat children with greater needs. In one example, the only bilingual specialist the facility could locate was in a neighboring State.

Finally, staff reported lack of therapeutic placement options within the ORR network that were equipped to treat children who needed a higher level of care. This was especially acute for children who needed secure therapeutic settings due to their history of behavioral problems.

To address these systemic challenges, we recommend that ORR leverage the expertise and resources within HHS and the broader mental health community, to ensure facilities have sufficient clinical staff who are fully supported and able to access the needed specialty care for children. These systemic challenges, according to staff, were exacerbated by policy changes made in 2018.

In the spring of 2018, the Department of Homeland Security formally adopted the zero tolerance policy of criminally prosecuting all adults for illegal entry and placing their children in ORR facilities. Facilities reported that addressing the needs of children separated from their parents was particularly challenging, because the children exhibited more fear, more feelings of abandonment, more post-traumatic stress than children who were not separated.

One medical director told us that separated children would present physical symptoms as manifestations of their psychological pain. These children would say their chest hurts even though there was nothing wrong with them medically. One child even said, every heartbeat hurts.

These children didn't understand why they were separated. As a result, some were angry, believing their parents had abandoned them. Others were anxious, concerned for their parents' safety. One 8-year-old boy, who the chair talked about, was separated from his father, was under the delusion that his father was killed and that he was next, and he required emergency psychiatric care.

Caring for separated children was additionally challenging, because they were often younger than the teenagers the facility were used to serving. Staff reported younger children had shorter attention spans, needed greater supervision, and more commonly exhibited defiance and other negative behaviors. They couldn't always accurately communicate. The little ones, as one program director said, don't know how to express how they are feeling.

There were other policy changes in 2018 as well, and these involved the process for discharging children to sponsors. ORR added new screening requirements and started sharing sponsor information with immigration officials. Staff noted that these changes led to longer stays in care for children, and that had a negative effect on their behavior and their mental health. They said, even children who entered care with good coping skills became disillusioned as their time in care dragged on, resulting in higher levels of hopelessness, frustration, and more instances of self-harm.

While the policy changes made in 2018 have largely been reversed, facilities continue to serve separated children as well as children who are not quickly discharged from care. To address these continuing challenges and to ensure that children are not unnecessarily harmed, we recommend that ORR continue to reassess whether its current policies are negatively impacting children in any way and adjust as needed. We also recommend that ORR establish guardrails that ensure that future policy changes prioritize child welfare considerations above all other competing demands.

Thank you to the committee for the opportunity to present this information and your ongoing support of our oversight. It is greatly appreciated. I am happy to answer any questions you have.

[The information follows:]



Testimony of

Jonathan H. Hayes

Director

Office of Refugee Resettlement

Administration for Children and Families

U.S. Department of Health and Human Services

Before the

Committee on Appropriations

Subcommittee on Labor, Health and Human Services,

Education, and Related Agencies

United States House of Representatives

September 18, 2019

Chairwoman DeLauro, Ranking Member Cole, and Members of the Committee, it is my honor to appear before this subcommittee, on behalf of the Department of Health and Human Services (HHS). My name is Jonathan Hayes. As the Director of the Office of Refugee Resettlement (ORR), I oversee the Unaccompanied Alien Children (UAC) Program.

I am joined today by Commander Jonathan White, an Officer in the U.S. Public Health Service Commissioned Corps, currently assigned to the Office of the Assistant Secretary for Preparedness and Response at HHS. Commander White is a clinical social worker and emergency manager and served as the Federal Health Coordinating Official for the interagency mission to reunify children separated from their parents in ORR care as of June 26, 2018. He also previously served as the Deputy Director at ORR. He has not prepared written testimony but is here to answer your questions.

Thank you for the opportunity to discuss with you today the HHS Office of Inspector General (OIG) report titled, "Care Provider Facilities Described Challenges Addressing Mental Health Needs of Children in HHS Custody." HHS is committed to addressing the mental health needs of UAC in the custody of ORR. We welcome the report as we continually improve the mental health services provided to the children in our care.

I will start with a brief overview of the UAC program. I will then address OIG's findings and recommendations and inform the subcommittee on current and future ORR activities to strengthen mental health care for UAC in HHS care and custody.

Program Overview

HHS operates nearly 170 state-licensed care provider facilities and programs in 23 states. HHS has different types of facilities, including group homes; long-term, therapeutic, or transitional foster care; residential treatment centers; staff-secure and secure facilities; and shelters in order to meet the different needs of the minors in our care. ORR awards grants to independent service providers who operate programs to support UAC on ORR's behalf. ORR grantees operate the facilities, which are licensed by the responsible state agency. Every state has its own licensing standard. Even within a state, different types of facilities may not be licensed by the same state agency or be required to follow the same regulations and standards as other facilities. However, all programs must follow ORR policy with respect to the care of UAC in HHS custody.

In addition to our traditional state-licensed facilities, ORR also operates influx care facilities, which receive UACs when ORR's licensed bed capacity is strained by surges of referrals. HHS has detailed policies for when children can be sheltered at a temporary influx care facility. The minor must be between 13 and 17 years of age; have no known special medical or behavioral health conditions; have no accompanying siblings age 12 years or younger; and be able to be discharged to a sponsor quickly, among other considerations.

These facilities by their nature as emergency facilities are not required to be state-licensed; however, they must adhere to ORR policies and provide required services. ORR strives to provide a quality of care at temporary influx care facilities that is parallel to our state-licensed programs. Children in these facilities can participate in recreational activities and faith-based services, and

they receive case management, on-site education, medical care, legal services, and counseling. ORR also requires influx facilities to have emergency clinical services available if needed. ORR will transfer a child out of an influx facility based on the needs of that child.

Mental health services are available at all of our facilities. ORR policy requires, at a minimum, that UAC in ORR state-licensed facilities receive an individual counseling session and two group counseling sessions with a clinician every week. Additional mental health services are available as needed.

ORR also requires facilities to provide routine medical and dental care, educational services, legal services, and recreational activities such as arts and crafts and large muscle activity.

The children in ORR custody have a unique set of needs. ORR provides services to children from a wide range of backgrounds and cultures who speak a variety of languages. As documented in the OIG report, many of the children placed in ORR custody are victims of violence and abuse and have experienced severe trauma in their countries of origin and during their journeys to the United States. The mental health professionals working with UAC must be bilingual and be qualified to assist traumatized children, yet the OIG report acknowledges the general shortage of qualified practitioners. There is a greater shortage of pediatric mental health practitioners, and that shortage is even greater given the language skills which are also needed. Those qualification requirements create great difficulties in both recruiting on-site staff as well as finding referrals for additional services in the communities around the facilities.

Further complicating the recruitment of qualified mental health practitioners is the location of most ORR facilities. The Flores Settlement Agreement (FSA), which created the framework for ORR services, includes a requirement that the government make reasonable efforts to find licensed facilities near the locations where a majority of UAC are encountered. As a result, most ORR facilities are near the Southern border in rural areas that tend to lack mental health services generally, let alone the specialized services required for UAC. OIG recognized this shortage of services in its report.

ORR is committed to facing and overcoming these challenges. We have already taken steps to address many of the concerns described in the report, including greatly reducing average length of time a child spends in ORR custody.

I would like to thank Congress for assisting in these efforts and, in particular, the \$4,000,000 appropriated in Fiscal Year 2019 to the National Child Traumatic Stress Initiative, a program within the Substance Abuse and Mental Health Services Administration (SAMHSA), for mental health services for UAC. ORR is collaborating with the National Child Traumatic Stress Network (NCTSN), a grantee of SAMHSA, to expand mental health services for UAC. ORR is looking forward to continuing to work with both government and non-governmental partners to strengthen mental health services for UAC. I also hope Congress will continue to support these efforts.

Report Methodology

Before discussing the specifics of the OIG report, I would like to address the methodology of the report that OIG itself identified. First, the report is a qualitative analysis from interviews with program staff and federal staff, examination of employee records, and OIG's own assessment of the facilities. OIG did not independently verify the information that was provided in these interviews. Nor did OIG independently review health records or perform clinical assessments of the quality or reasonableness of the services provided to UAC. Additionally, OIG did not investigate whether programs were in compliance with ORR policies related to mental health. OIG visited 45 sites in the ORR network, so the report's findings do not reflect the experience of all ORR providers. Finally, the OIG investigation took place at a time when ORR was experiencing changes to the UAC population that were outside of ORR's control. As the report notes, at the time of the investigation, ORR was experiencing a surge of UAC referrals generally, and in particular, a high number of referrals of young children. The increased demand, especially for age-appropriate services for young children, created additional challenges for ORR and care providers.

The methodology provides the context necessary to better understand the findings and recommendations in the report. I will now address each recommendation and the findings associated with that recommendation, and will describe ORR's current activities related to that recommendation.

Report Recommendations

Recommendation 1: Identify and disseminate evidence-based approaches to addressing trauma in short-term therapy.

One challenge identified in the report is that some clinician staff told OIG that they are often unprepared to assist children with the severe trauma experienced by UAC. The report documented that some clinicians felt they were unprepared for the level of trauma experienced by the children and the toll that would take on their own mental health. Treating children with severe trauma is complicated and is only made more complicated by the relatively short amount of time children reside in ORR custody – ORR’s average length of care as of August 31, 2019 is 50 days. Some clinicians told OIG that they were concerned about asking children to revisit their trauma when it was unclear whether the child would be in custody long enough to make progress in addressing their trauma fully.

ORR’s mission remains to unify children with a suitable sponsor as expeditiously and safely as possible. For this reason, most children do not stay in ORR care for long periods. Based on the clinical expertise of the mental health professionals on staff, the focus of mental health services has been to stabilize children and provide them with a sense of security. However, program staff assess each child’s mental health needs and provide additional services as appropriate.

ORR is working to provide clinicians with tools to strengthen mental health services. Recently, ORR collaborated with the NCTSN to develop a 4-part webinar series on addressing trauma in UAC. The webinar covers trauma 101, building cultural competence, and recommendations for reducing providers’ own stress. The webinar also provides information on recognizing trauma in

older children, and there is a separate portion on recognizing trauma in children under 6 years of age. The webinar is available online through the NCTSN Learning Center and participants may receive continuing education credits for completing the courses. ORR is working with NCTSN to develop additional resources.

ORR also offers post-release services (PRS) to some UAC. If a child does need mental health services after they leave ORR care, a PRS caseworker will work with both the child and the sponsor to find services in their community. The caseworker meets with the child and the sponsor to ensure the child's needs are being met. ORR is working to expand the number of UAC that receive PRS.

Recommendation 2: Develop and implement strategies to assist care provider facilities in overcoming obstacles to hiring and retaining qualified mental health clinicians.

OIG identified significant external challenges to hiring and retaining qualified mental health clinicians. These challenges include finding bilingual staff with the experience and qualifications necessary to work with UAC in the locations surrounding ORR-funded facilities. In addition to finding applicants with the right set of qualifications, public misunderstanding about ORR and the UAC program has also made recruitment more difficult. For example, contrary to some reports in the press, HHS does not apprehend migrants at the border, nor does it enforce immigration laws. The Department of Homeland Security (DHS) and the Department of Justice (DOJ) perform those functions. Also, ORR does not have jurisdiction over children who arrive with an adult parent; DHS is responsible for these families. HHS' UAC Program is a humanitarian child welfare

program, designed for the temporary care of UAC until they can be safely released or unified with family or other sponsors.

ORR is working on a number of strategies to address these challenges including developing an internship program so that colleges and universities can place interested students in ORR facilities. ORR is working to increase its presence at job fairs in the areas where recruitment has been difficult to assist programs in outreach to potential candidates. ORR is also providing additional funding for continuing education programs for clinicians.

Recommendation 3: Assess whether to establish maximum caseloads for individual mental health clinicians.

ORR currently has a staffing ratio of one clinician for every 12 children; however, OIG noted that there is no maximum caseload for clinicians. Despite the staffing ratio, clinicians may have different caseloads based on the demand for services. For example, one clinician may have a smaller caseload because of the significant mental health needs of one child, so another clinician may accommodate a larger caseload.

ORR will evaluate the current ratio policy with input from subject matter experts both within HHS and outside the agency. ORR will also determine whether a maximum caseload requirement is needed in addition to a staffing ratio. ORR is hopeful that the recruitment efforts discussed above will help more evenly distribute caseloads among staff clinicians.

Recommendation 4: Help care provider facilities improve access to mental health specialists.

As I mentioned before and OIG notes in the report, there is a national shortage of qualified mental health professionals, especially bilingual ones. This not only affects ORR's ability to recruit qualified staff to work at facilities, but also its ability to find mental health professionals to provide specialized treatment that cannot be provided by facility staff. The negative public perception of ORR which stems from inaccurate or misleading reporting about the UAC program also hinders recruitment.

ORR allows programs to seek services from providers outside of ORR's network to meet the health needs of UAC in care. ORR has an underwriter that identifies and facilitates referrals to providers. The Division of Health for Unaccompanied Children (DHUC) at ORR works with ORR's underwriter to identify additional providers in areas surrounding ORR facilities. DHUC also identifies tele-health providers that can provide appropriate services when in-person options are not available.

Recommendation 5: Increase therapeutic options for children who require more intensive mental health treatment.

One type of facility that ORR operates are residential treatment centers (RTCs). RTCs are specialized facilities providing higher levels of care for children who require it. There are two RTCs in the ORR network, although programs can refer UAC to out-of-network RTCs as necessary. The *Flores* court approved ORR policy which requires a referral from a licensed

psychologist or psychiatrist, and additional approvals are required at the ORR headquarters level before a child can be placed in an RTC. These requirements ensure it is in the best interest of the child to be placed in an RTC. Further, DHUC provides training to Federal Field Specialists on the appropriate use of RTCs, pursuant to which referral to an RTC should only be considered after all appropriate out-patient services have been exhausted. The small number of RTC beds can also slow transfer of UAC to these facilities when deemed appropriate. ORR continues to engage new providers to add capacity.

Recommendation 6: Take all reasonable steps to minimize the time that children remain in ORR custody.

OIG identified that the longer a child remains in custody, the more significant their mental health needs become.

I believe that a child should not remain in ORR care any longer than the time needed to find an appropriate sponsor for the child. A central part of ORR's mission is to release children from custody as quickly as possible while still ensuring the safety of the child.

To that end, and during my tenure as Director of ORR, we have issued four operational directives and revised our policies and procedures with the specific aim of a more efficient and safe release of UAC from our care and custody. These directives followed an assessment of ORR's operations to see if the current policies and procedures were necessary for the safety of children. Based on that assessment, ORR concluded that operations could be modified to both ensure safe releases as

well as timely ones. Following the directives, the average length of care dropped. At the time OIG conducted its visits, the average length of care was 83 days. It is now 50 days, a 40% reduction. ORR will continue to assess the efficiency of its operations to improve the process for release and reduce the time a child remains in custody.

Conclusion

My top priority and that of my team is the safety and well-being of children in the temporary care of HHS. We welcomed this report because it explained the services ORR currently provides and identified the obstacles we face in providing those services. My team is ready to face those obstacles and overcome them with help from our partners and with the continued support of Congress.

Thank you for the opportunity to discuss our important work. Commander White and I will be happy to answer any questions you may have.

Jonathan H. Hayes

Jonathan serves as the Director of the Office of Refugee Resettlement (ORR) in the Administration for Children & Families at the Department of Health & Human Services (HHS). Prior to being named the Acting Director in November 2018 and the Director in February 2019, he served as the Chief of Staff for ORR, serving in the Office of the Director.

Prior to joining HHS, Jonathan served as chief of staff to two members of congress spanning over eight years. Additionally, he has experience in the private sector working in broadcast television, sales, marketing, international trade and customs and commercial airline operations.

Jonathan received his Bachelor of Science Degree in Business Administration from Florida State University.

Born in Greenwood, Mississippi and raised in Panama City, Florida – he now lives in northern Virginia with his wife Tammy and their five children.

Commander Jonathan White, Ph.D., LCSW-C, CPH is a career officer in the U.S. Public Health Service Commissioned Corps and a Maryland licensed certified social worker-clinical. He is an emergency manager specializing in the needs of children and vulnerable populations in crisis events. He is currently stationed in the HHS Office of the Assistant Secretary for Preparedness and Response as the Director of Recovery in the Office of Emergency Management and Medical Operations. He led the mission to reunify children separated from their parents at the U.S. border as the Federal Health Coordinating Official/HHS Operational Lead for the reunification mission. Prior to joining ASPR, he was the Deputy Director for Children's Programs in the Administration for Children and Families (ACF) Office Of Refugee Resettlement (ORR), where he led the Unaccompanied Alien Children Program, which provides care and services to 40,000-60,000 children and youth annually who enter the U.S. without parents or legal guardians. He previously served as Senior Adviser in ACF's Immediate Office of the Assistant Secretary, responsible for crisis management, public health, and strategic initiatives. Prior to that he served as Deputy Director of ACF's Office of Human Services Emergency Preparedness and Response. Earlier in his social work career he was an oncology social worker with the National Institutes of Health Clinical Center, working with advanced cancer patients and their families. Previous to his social work career he was a college professor and labor union campaign staffer. He has deployed or held national-level leadership roles in over 50 domestic disaster, public health emergency, UAC influx, and programmatic crisis events.

Ms. DELAURO. Many thanks.

Director Hayes, welcome back. Thank you for being here and, again, your full testimony will be in the record. And so now I will recognize you for 5 minutes.

Mr. HAYES. Thank you, Chairwoman DeLauro, Chairwoman Lowey, and Ranking Member Cole, members of this committee. It is my honor to appear today on behalf of the Department of Health and Human Services. My name is Jonathan Hayes, and as the Director of the Office of Refugee Resettlement, I oversee the Unaccompanied Alien Children Program.

I am joined today by Commander Jonathan White, an officer in the U.S. Public Health Service who is currently assigned to the Assistant Secretary for Preparedness and Response at HHS. Commander White served as the Federal Health Coordinating Official for the interagency mission to reunify children separated from their parents in ORR care as of June 26, 2018. He also previously served as a deputy director at ORR. He has not prepared testimony, but is here to answer your questions.

Thank you for the opportunity to discuss with you today the HHS Office of Inspector General report titled "Care Provider Facilities Described Challenges Addressing Mental Health Needs of Children in HHS Custody." HHS is committed to addressing the mental health needs of the UAC in the care of ORR. We welcome the report as we continually improve the mental health services provided to the children in our care.

ORR operates nearly 170 State-licensed care provider facilities and programs in 23 different States. ORR has different types of facilities in order to meet the different needs of the minors in our care. In addition to our traditional State-licensed facilities, ORR also operates influx care facilities which receive UAC when ORR's licensed bed capacity is strained by surges of referrals or in a case of a natural disaster or other emergency.

HHS has detailed policies for when children can be sheltered at a temporary influx care facility. Mental health services are available at all of our facilities. ORR policy requires, at a minimum, that UAC and ORR State licensed facilities receive an individual counseling session and two group counseling sessions with a clinician every week. Additional mental health services are available as needed.

The children in ORR care have a unique set of needs. We provide services to children from a wide range of backgrounds and cultures who speak a variety of languages. As documented in the OIG report, many of the children placed in ORR care have experienced severe trauma. The mental health professionals working with the children must be bilingual and be qualified to assist traumatized children. Yet, the OIG report acknowledges the general shortage of qualified practitioners nationwide.

The qualification requirements create difficulties in both recruiting on-site staff as well as finding referrals for additional services in the communities around the facilities. One challenge identified in the report is that some clinician staff told the OIG that they are often unprepared to assist children with the severe trauma experienced by UAC.

Treating children with severe trauma is complicated and is only made more complicated by the relatively short time of children residing in ORR care. Some clinicians told OIG that they were concerned about asking children to revisit their trauma when it was unclear whether the child would be in our care long enough to make progress in addressing their trauma fully.

ORR's mission remains to unify children with a suitable sponsor as expeditiously and safely as possible. For this reason, most children do not stay in ORR care for very long. Based on the clinical expertise of the mental health professionals on staff, the focus of mental health services has been to stabilize children and to provide them with a sense of security. However, program staff assess each child's mental health needs and provide additional services, as appropriate.

ORR is working to provide clinicians with tools to strengthen mental health services. Recently, ORR collaborated with the National Child Traumatic Stress Network, or NCTSN, to develop a four-part webinar series on addressing trauma in UAC. ORR is continuing to work with the NCTSN to develop additional resources. ORR also offers post-release services to some UAC.

If a child needs additional mental health services after they leave ORR care, a post-release services caseworker will work with both the child and the sponsor to find services in their community. ORR is working to expand the number of UAC that receive post-release services.

I believe that a child should not remain in ORR care any longer than the time needed to find an appropriate sponsor for the child. A central part of ORR's mission is to discharge children from our care as quickly as possible while still ensuring the safety of the child. At the time that OIG conducted its visits, the average length of care was 83 days. It is now 50 days, a 40 percent reduction. ORR will continue to assess the efficiency of its operations, to improve the process for release and reduce the time that a child remains in our care and custody.

My top priority and that of my team is the safety and well-being of the children in the temporary care of HHS. We welcome this report, because it explained the services that ORR currently provides and identified the obstacles that we face in providing those services. My team is ready to face those obstacles and overcome them, with help from our partners and with the continued support of Congress.

Thank you for the opportunity to discuss our important work. Commander White and I will be happy to answer any questions that you and your committee may have. Thank you, Chair DeLauro.

[The information follows:]

Testimony of:

Ann Maxwell

Assistant Inspector General for Evaluation and Inspections

Office of Inspector General, U.S. Department of Health and Human Services

Good morning, Chair DeLauro, Ranking Member Cole, and Members of the Committee.

I am Ann Maxwell, Assistant Inspector General for Evaluation and Inspections for the Office of Inspector General (OIG), U.S. Department of Health and Human Services (HHS). I appreciate the opportunity to appear before you to discuss the challenges that care provider facilities faced addressing the mental health needs of children in HHS custody. Any significant challenges that facilities face in addressing a child's mental health needs could have serious immediate and long-term ramifications for children's well-being.

OIG's Oversight

OIG oversees all HHS programs and operations. OIG combats fraud, waste, and abuse in those programs; promotes their economy, efficiency, and effectiveness; and protects the beneficiaries they serve. To accomplish this, OIG employs an array of tools, including audits, evaluations, and investigations.

OIG takes very seriously its responsibility to protect the health and welfare of vulnerable children. As such, we have prioritized oversight of the Unaccompanied Alien Children (UAC) Program, which is administered by the Office of Refugee Resettlement (ORR) within HHS's Administration for Children and Families (ACF), since responsibility for caring for unaccompanied children was transferred to HHS by the Homeland Security Act of 2002.

One important goal of OIG's work on the UAC Program has been to promote the protection of children in HHS care. We have reviewed whether ORR grantees met safety standards for the care and release of children in their care, and the efforts of ORR to ensure the safety and well-being of children after their release to sponsors.

In 2018, numerous stakeholders raised serious concerns about the health and safety of unaccompanied children, including the provision of appropriate mental healthcare services, at HHS-funded facilities. Given the urgency of the situation, and OIG's independent oversight role, we launched a series of reviews examining health and safety issues in the UAC Program. This testimony focuses on challenges to providing mental health services. Other reviews from our 2018 initiative address employee screening, including staff background checks, physical security of facilities, and challenges facilities faced in ensuring children's safety. We are also assessing the challenges HHS and facilities faced in reuniting separated children with their parents.

ORR's Unaccompanied Alien Children Program

The UAC Program serves children who have no lawful immigration status in the United States and no parent or legal guardian available to provide care and physical custody. By law, ORR has custody of and must care for each unaccompanied child by providing housing, food, educational services, recreational activities, and health services, including mental health services.

ORR funds a network of more than 100 facilities that furnish care for children until they are released to a sponsor or otherwise leave ORR custody. These facilities, generally, are State-licensed and must meet ORR requirements. Most children are in shelter facilities, the least restrictive setting. ORR's network also includes residential treatment centers that provide therapeutic care, as well as secure and staff secure facilities that provide a higher level of supervision. One of the staff secure facilities also offers specialized therapeutic care.

Mental Health Services in Care Provider Facilities

According to the terms of the 1997 Flores Settlement Agreement, which sets national standards for the detention, release, and treatment of children without legal immigration status in

Federal custody, children must receive necessary medical and mental health services. At a minimum, each child in ORR custody must receive at least one individual counseling session per week from a trained mental health clinician. When needed, children also may receive care from external mental healthcare specialists, such as psychiatrists and psychologists.

Mental health clinicians are employed at every facility and are responsible for providing in-house mental healthcare for children. These clinicians, who must meet minimum education and experience qualifications, are responsible for conducting mental health assessments, providing counseling services, providing crisis intervention services, and recommending care from external specialists. ORR requires each facility to employ at least 1 mental health clinician for every 12 children in care.

HHS-OIG Review of Mental Healthcare Challenges in ORR-Funded Facilities

To complete this review, OIG conducted site visits at 45 of the 102 ORR-funded facilities that were in operation in August and September of 2018. We visited facilities to hear directly from their staff about the challenges they faced caring for children and ensuring their safety.

Facilities were purposively selected to achieve wide coverage of facilities participating in the UAC Program, varying by size and geographic location, among other factors. These facilities cared for about 72 percent of children in ORR's custody at the time of our review.

We conducted qualitative analysis of interview data from: (1) approximately 100 mental health clinicians who had regular interaction with children across the 45 facilities; (2) medical coordinators in each of the 45 facilities; (3) the program director and lead mental health clinician in each of the 45 facilities, and (4) the 28 ORR federal field specialists assigned to the 45 selected facilities.

We did not determine whether the challenges that were identified resulted in care that failed to meet ORR requirements or clinical standards, nor did we assess the quality of the mental healthcare provided. Instead, we offer a broad survey of the challenges facing the program as reported by staff in order to provide ORR with information useful for directing attention toward the most significant mental health-related challenges facing facilities.

Report Findings and Recommendations

Facilities reported several challenges in addressing children's mental health needs. Some were systemic in nature, such as: (1) the inherent challenges associated with treating children who have experienced intense trauma, (2) difficulty accessing external mental health specialists, and (3) difficulty finding therapeutic placement options within ORR's network. In 2018, existing challenges were exacerbated by Federal policy changes that resulted in facilities caring for an increasing and changing population, including younger children who were unexpectedly separated from their parents. We recommend practical steps ORR can take to assist facilities and address these challenges.

Mental Health Clinicians Stated That They Were Not Prepared To Care for Children Who Had Experienced Intense Trauma

Facility staff discussed the challenges inherent in caring for a population of children who have experienced intense trauma. Facility staff reported that many of the children in their care had experienced intense trauma from a variety of events in their home countries or on their journey to the United States. Some children experienced additional trauma when they were unexpectedly separated from their parents upon arrival in the United States.

Despite their training and experience, mental health clinicians reported feeling unprepared to address the level of trauma that some children had experienced.¹ The UAC Program is designed to house and care for children during relatively short-term stays until they can be released to sponsors. Because the length of children's stays are unpredictable and, from a mental health treatment standpoint, relatively short, mental health clinicians reported being unable to adequately address their trauma. Mental health clinicians reported that they were wary of opening wounds that they would not have time to address adequately through continued therapy and, instead, focused on making sure that children were stable and able to cope day-to-day.

All facilities reported that staff—including mental health clinicians—received training to help them work with children who had experienced trauma. Nonetheless, mental health clinicians discussed how challenging it was to hear about children's traumatic experiences. Further, mental health clinicians said that colleagues hired without previous experience in caring for unaccompanied children in ORR custody may have been especially unprepared for the severe trauma of children in their care. Mental health clinicians and program directors told us that facility staff would benefit from more training on trauma-informed care.

OIG recommends: Additional guidance on addressing trauma in children. To

address these issues, we recommend that ORR provide facilities with evidence-based guidance on addressing trauma in short-term therapy in children of all ages.

¹ Our companion review: *Unaccompanied Alien Children Care Provider Facilities Generally Conducted Required Background Checks but Faced Challenges in Hiring, Screening, and Retaining Employees* found that almost all the facilities we visited hired mental health clinicians who met minimum requirements.

High Counseling Caseloads Stretched In-House Mental Health Clinicians

Care provider facilities reported high counseling caseloads due to challenges in recruiting and retaining mental health clinicians. This made it more difficult for them to make sure that all children received the time and attention they needed. Even facilities that met ORR's required facility-wide ratio of 1 clinician for every 12 children may have had individual clinicians who were responsible for counseling more than twice that number because of the way cases were distributed.

OIG also found that, at the time of our visits in August and September 2018, 26 of the 45 facilities reported that the mental health clinician position posed the greatest hiring challenge. Facilities most often attributed this to difficulties finding bilingual candidates and candidates who met the minimum qualifications.

OIG recommends: Strategies for addressing high mental health clinician caseloads.

We recommend that ORR assess whether to establish maximum caseloads for individual mental health clinicians. We also recommend that ORR develop and implement strategies to assist care provider facilities in overcoming obstacles to hiring and retaining qualified mental health clinicians.

Facilities Faced Challenges Accessing External Specialists for Children Who Needed Specialized Diagnosis and Treatment

We found that facilities faced challenges accessing external specialists for children who needed more mental health treatment than was available from in-house staff. ORR uses an insurance company that maintains a network of doctors, hospitals, and other health professionals to provide mental health services to children in ORR custody. However, facility staff told us that this provider network does not include enough mental health specialists to meet children's needs.

These challenges were acute for facilities in medically underserved areas. Bilingual specialists, in particular, were difficult to find.

OIG recommends: Strategies for improving access to external mental health

specialists. ORR should ensure that the national network of external healthcare providers maintained by its insurer includes the mental health specialists needed to address children's mental health needs. For facilities in areas with a scarcity of mental health specialists, ORR could consider entering into agreements with Federal, State, or local health agencies or qualified specialists to provide necessary mental health treatment.

Facilities Were Unable To Transfer Children Who Needed a Higher Level of Mental Healthcare to More Appropriate Placements Within ORR's Network

Mental health clinicians determined that some children needed a higher level of care than facility staff and external specialists could provide, but facilities reported difficulties transferring these children to facilities in the ORR network that are licensed to provide specialized care. Staff said that the two residential treatment facilities in ORR's network lacked bed space for children who needed transfers. Combined, these two facilities have 50 beds dedicated to children in ORR care.

Facility staff also described difficulty in finding appropriate placements for children who needed more therapeutic treatment but who also had a history of problem behaviors that put themselves or others at risk. Children with significant mental health needs such as oppositional defiant disorder, dissociative symptoms, and suicidal ideation remained in settings not well equipped to address their needs.

OIG recommends: Increased options for therapeutic placements in ORR's network.

ORR should increase therapeutic placement options for children who require more

intensive mental health treatment, including options for children with behavioral issues that accompany their mental health needs.

Federal Policy Changes Exacerbated Existing Challenges in 2018

Policy changes in 2018 exacerbated existing challenges, as they resulted in 1) a rapid increase in the number of children separated from their parents after entering the United States, many of whom were younger, and 2) longer stays in ORR custody for children.

Separated and Younger Children. According to program directors and mental health clinicians, separated children exhibited more fear, feelings of abandonment, and post-traumatic stress than did children who were not separated. Separated children experienced heightened feelings of anxiety and loss as a result of their unexpected separation from their parents after their arrival in the United States. In addition, the trauma of their separation, and resulting feelings of distrust, made it difficult for mental health clinicians to establish therapeutic relationships through which they could address children's needs.

In addition, the number of young children, age 12 and younger, in ORR's care increased sharply in May 2018 when the Department of Homeland Security (DHS) formally adopted the zero-tolerance policy of criminally prosecuting all adults for illegal entry into the United States. This policy led to many more children, some of them quite young, being separated from their parents. The proportion of young children in ORR care rose from 14 percent of referrals to ORR in April 2018 to 24 percent of referrals in May 2018.

Caring for young children presented different challenges than caring for the teenagers facilities typically served. Young children had shorter attention spans, lacked the ability to comprehend the role of the facility, and more commonly exhibited defiance and other negative behaviors. Facilities noted the difficulties associated with completing assessments and other

screenings for pre-school-aged and younger children who could not accurately communicate their background information, needs, or the source of any distress.

OIG recommends: Guidance that helps facilities care for young children. As previously mentioned, we recommend that ORR disseminate guidance on addressing trauma in short-term therapy. This guidance can improve facilities' readiness to meet the mental healthcare needs of children of all ages, including very young children.

Longer Stays in Facilities. A more stringent sponsor screening process led to longer stays in facilities. Facilities reported that children with longer stays experienced more stress, anxiety, and behavioral issues, which staff had to manage. Some children who did not initially exhibit mental health or behavioral issues began reacting negatively as their stays grew longer. Children who experienced longer facility stays exhibited higher levels of defiance, hopelessness, and frustration, along with more instances of self-harm and suicidal ideation.

ORR's requirements for screening potential sponsors have varied over time, as it attempts to balance safety concerns with the need for the timely release of children from HHS custody. In June 2018, ORR began requiring fingerprint background checks of all potential sponsors and the adult members of their households and sharing that information with DHS. Following this policy change, the amount of time that children remained in ORR care increased dramatically. In March 2019, ORR changed its policy again; it eliminated fingerprint background checks for parents or legal guardians, in most circumstances. By April 2019, the average length of stay had declined to 48 days. Since then, length of stay was 45 days in May and June and 47 days in July 2019.²

² The average length of time spent in care provider facilities by children who have been released from ORR custody. HHS, *Latest UAC Data- FY 2019*. <https://www.hhs.gov/programs/social-services/unaccompanied-alien-children/latest-uac-data-fy2019/index.html#>.

OIG recommends: Take reasonable steps to minimize the time that children remain

in ORR custody. It is essential that ORR appropriately assesses all sponsors before making a release determination. We recommend that ORR assess current policies and procedures to ensure that they do not present unnecessary barriers and establish procedures to ensure that future policy changes prioritize child welfare considerations and do not inadvertently increase the length of stay.

Conclusion and Upcoming OIG Work on the UAC Program

ACF concurred with all of our recommendations and described its plans to address them, some of which are underway. We encourage ACF to support the facilities that are directly responsible for the care of children in its custody and minimize barriers to appropriate mental health treatment.

OIG appreciates the support that we have received from Congress for our work overseeing the UAC program and the additional resources to augment our efforts in this area. We anticipate initiating reviews on new topics. Specifically, we expect to examine coordination between HHS and DHS, sponsor screening, emergency preparedness, and the appropriateness of children's placements and transfers within ORR's network of facilities.

Challenges to addressing the needs of children in HHS custody require our combined attention and very best efforts. Thank you for the opportunity to testify today and to be part of this conversation on this important topic.

Ann Maxwell
Assistant Inspector General for Evaluations and Inspections
Office of Evaluation and Inspections
Office of Inspector General
Department of Health and Human Services

Ann Maxwell is Assistant Inspector General for Evaluations with the Office of Evaluation and Inspections (OEI), Office of Inspector General (OIG), Department of Health and Human Services (HHS). She has been with OIG, in various roles, for 21 years.

OEI conducts national evaluations to provide HHS, Congress, and the public with timely, valuable, and reliable information on significant issues involving the numerous programs of HHS. These evaluations are objective, data-driven and evidence-based and focus on preventing fraud, waste, and abuse and promoting economy, efficiency, and effectiveness in HHS programs. This work helps ensure the wellbeing of recipients served by these programs. Ms. Maxwell is responsible for managing multiple subject-matter portfolios, including public health, Medicaid, food and drug safety, emergency preparedness, prescription drugs, and the safety of children. Ms. Maxwell also oversees the State Medicaid Fraud Control Units, which investigate and prosecute providers for Medicaid fraud as well as for patient abuse and neglect.

Ms. Maxwell has focused significant efforts on evaluating prescription drug benefits under Medicare, Medicaid, and the 340B Drug Pricing Program. Under her direction, evaluations of Medicaid drug pricing contributed to significant changes in the way Medicaid reimburses for prescription drugs. Another body of evaluation work resulted in strengthened oversight of the 340B Drug Pricing Program. She also directed sophisticated data analytic work evaluating the opioid crisis, including inappropriate prescribing and utilization as well as the availability of treatment. Most recently, Ms. Maxwell has directed a multidisciplinary team in reviewing the Unaccompanied Alien Children program. This work covers a broad variety of health and safety issues, including the background screening of facility staff that work with children, the challenges care facilities face in ensuring children are safe, and the physical security of the care facilities. This work also examines challenges ORR care provider facilities face in meeting children's physical and mental health care needs.

Ms. Maxwell's work has received numerous awards, including Bronze Medal for Exemplary Leadership, the Excellence in Program Evaluation Award, and the Award for Excellence in Evaluation granted by the Council of the Inspectors General on Integrity and Efficiency. In addition, Ms. Maxwell was awarded HHS-OIG's highest leadership award, the Thomas Morris Award, in March 2019, recognizing her long record of achievement in OIG and her leadership on a variety of important and high-profile projects impacting Department and national discussions.

Ms. Maxwell received a B.A. in Sociology and Economics from Kalamazoo College. She also holds a master's degree from the University of Chicago's School of Social Service Administration, where her studies focused on public policy and program evaluation.

Ms. DELAURO. Thank you very, very much.

I will get right to the questions here. Ms. Maxwell, you note that the policies that traumatize these children have largely been reversed, and I just pick up your quote at the end of your remarks. But you say that facilities still face challenges addressing the trauma of separated kids and that we ought to pay attention to that and to the deteriorating mental health of the kids who remain in care.

The policies have been reversed. What are still the challenges and what are the policies that ought to be examined going forward?

Ms. MAXWELL. Thank you, Chair, for allowing me to clarify that point. Yes, the additional challenges that facilities faced in 2018 continue to be a concern despite some of the policy reversals.

First of all, facilities continue to provide care for separated children. So the court order, as you mentioned, that stop most separations allows for separations under certain conditions.

Ms. DELAURO. There are separations.

Ms. MAXWELL. Absolutely. And the Federal Government recently certified to the Court that there were 911 children separated from a parent over the last year. In addition, with respect to lengths of stay, ORR did reverse additional sponsor screening requirements and the length of stay fell. However, they continue to share information about sponsors with DHS, according to the 2016 MOA and, again, as you mentioned, there are concerns that that has a chilling effect on finding sponsors, which is why we recommend that ORR review all of its current policies to see if they present any unnecessary barriers to releasing children to appropriate sponsors and adjust them as necessary.

Ms. DELAURO. Thank you for the clarity on that issue.

Let me move to exhibit 2 on page 12 of the report shows how the number of young children referred to ORR sharply increased as a result of family separation, and I want to put this information into the record.

ORR facilities typically serve teenagers. So answer to this question: Did facilities and grantees have the right tools to adequately provide mental health services for younger children?

Ms. MAXWELL. Not according to the clinical staff that we spoke to. They told us that they, as Director Hayes had mentioned, that they expressed their concerns about being able to treat children who had encountered intense trauma before coming into care. Now, this is a concern they had in terms of treating all children. They noted it was additionally challenging treating younger children, who had different needs and different therapeutic needs, and had less attention span.

So we recommend, again, that ORR help these facilities, help the clinicians by identifying and disseminating evidence-based, trauma-informed, short-term therapy for children of all ages.

Ms. DELAURO. Thank you.

Commander White, earlier the subcommittee held a hearing with Dr. Altha Stewart, who is president of the American Psychiatric Association. Told us about toxic stress. Highly stressful experiences like separation of children from their family is resulting in toxic stress, can cause irreparable harm.

I respect the testimony that I have heard that you have provided in previous hearings and the warnings that you gave to HHS officials about the traumatic impacts of family separation and the effect on children.

Let me just ask you, with your medical background, with what you know about the children who end up in ORR's care, what can you tell us about toxic stress that affects these children as a result of the trauma they have experienced in their countries of origin, during the journeys to the United States, and as a result of family separation?

Mr. WHITE. Thank you, Madam Chairwoman. So, to be clear, the UAC program has long been trauma-informed and is designed to serve unaccompanied children. That is an enormous challenge. It is an enormous challenge. But it is dwarfed by the unique challenge of separated children. And, as I have testified in front of other committees and I will say again today, it is in my professional judgment impossible to build a program that can respond appropriately to the needs of separated children.

The only way to address that trauma is prevention. And this speaks to the need for a coherent legislative fix to define those conditions under which it is permissible to separate a child from a parent at the border, to have appropriate rights and remedies for parents who experience that.

The UAC program is the right place for children who enter the United States unaccompanied, but neither it nor any other Federal program I could imagine can respond to the recentness, the severity, the toxicity of the trauma of separation from parents, particularly when the clinicians themselves will be seen by the children as part of the very system that separated them.

Ms. DELAURO. Thank you. I am going to go for the last comment here. You have exhibit 3, page 13 of the report: Length of stay in ORR custody spiked after HHS signed the MOA with DHS. So, Ms. Maxwell, according to the mental health clinicians your investigators interviewed, what are the mental health effects on children saying in ORR custody longer as a result of the memorandum of agreement?

Ms. MAXWELL. What we heard from clinicians in the field were that children who did not initially exhibit mental health or behavioral issues began reacting negatively the longer their stay wore on.

Ms. DELAURO. So the longer children stay in care, the longer they are traumatized. Let me make a final comment here. As long as the MOA is still in place, there are sponsors who are terrified of coming forward. It was at our July hearing Assistant Secretary Johnson agreed that HHS should be terminated. As long as this MOA is in place, HHS is unnecessarily extending ORR custody for children, which further traumatizes them. The MOA must be rescinded.

Congressman Cole.

Mr. COLE. Thank you very much, Madam Chair.

Ms. Maxwell, let me start with you, if I may. You had some really valuable, I think, and very helpful information on the damage done, in terms of family separation to young children.

We obviously have a larger population that is unaccompanied, and so they don't review that, but if you could distinguish, and the last testimony actually probably did a pretty good job of this, but that second population which we are dealing with in very large numbers, what are the differences that you see between, obviously, family separation, which I think we all agree was a bad mistake, and, obviously, the more normal situation that we are now dealing with of unaccompanied children? Are they traumatized to the same extent?

Ms. MAXWELL. Yes. Thank you for that question. Yes, our report largely deals with the entire population of children that the ORR facilities have to provide mental healthcare. Most of the challenges that we heard about were, in fact, systemic challenges that affected all the children in care. And we heard again and again that all the children in care suffered, you know, severe trauma in home country, during the journey, and that some children experienced the additional trauma of unexpectedly being separated from their parents.

But as we move forward with our recommendations on practical steps that ORR can take to address these systemic challenges, we have designed them such that they would help improve the mental healthcare for all the children that ORR facilities are responsible for caring for.

Mr. COLE. Thank you.

Director Hayes, could you give me some idea of the steps that you have taken to respond to some of the suggestions and recommendations that the IG has placed in front of you?

Mr. HAYES. Yes, sir, Congressman, I am happy to. So, again, we are working on a number of things in response to the OIG's report. We already are working on developing an intern program with colleges and universities in order to place interested students in ORR programs, with hopes that they will one day come and join us as professionals postgraduate. Additional funding for continuing education to license clinicians as a retention strategy is also something that we are undertaking.

We are working to expand our presence at job fairs across the Nation in order to find needed clinicians and case managers to work in our facilities, although I will note that a number of those job fairs have been protested and some of the staff verbally—potential staff verbally threatened, and so that is not helpful.

We have also partnered with the National Child Traumatic Stress Network, the NCTSN, to develop a four-part webinar series, as I referenced in my testimony, on trauma in the UAC. And in April of 2019, we also hired a board certified adolescent and adult psychiatrist that is employed inside of the Division of Health of Unaccompanied Children at ORR.

Mr. COLE. I commend you for those steps.

Let me go back very quickly to Ms. Maxwell. Do you have a mechanism to follow up? I think there is a good faith effort going on at ORR to try and respond, but, you know, it is important, obviously, that we have, as you provided us, sort of an outside view to make sure that that process continues.

Ms. MAXWELL. Absolutely. Thank you. We are happy to see the steps that ORR has already committed to, some of which they have

already undertaken. So that is a good start. But yes, our process is to always follow the recommendations and be in conversation with the Department, to ensure that all of the commitments that they made are fulfilled and are fulfilled to sort of the spirit of the recommendation as well. So we will continue to work with the Department to make sure.

Mr. COLE. And I hope you, as I know you will, stay in touch with this committee because, obviously, at the end of the day we have got a resource requirement here.

Let me go back to you, if I may, Director Hayes. It has got to be extraordinarily difficult to get the personnel you need. We know that, as I mentioned earlier, just in terms of mental health for the entire population. In this case, you need bilingual professionals, I would suspect, in many cases. There can't be a ton of those, particularly in a lot of the areas that you have your shelters. So, I mean, number one, what are you doing? What level of success are you having?

Mr. HAYES. So thank you, Congressman. Yes, to your point, you know, the Flores settlement agreement does require the majority of our shelters to be in the area where the majority of the children are apprehended: Southeast Texas, the northeast corridor, southern Florida and southern California. And so, you know, there is a challenge in those areas to identify and retain some of the licensed clinicians that we need. We are looking to expand outside of some of those areas.

We work very closely with keeping the committee staff informed on our efforts to look into larger metropolitan areas, where we can have some of these smaller and medium-size shelters and then, you know, hopefully tap into a fresh, you know, pool of clinician staff, although we are seeing some resistance to that even right here in our own backyard in DC and Northern Virginia.

You know, again, at the express desire of Congress to open up more smaller and medium size shelters that are licensed, we are seeking to do that and not really receiving a lot of support, actually opposition by both D.C. and Northern Virginia.

So we will continue to look in other areas and expand outside of that, but we can pull, you know, from the local community the needed licensed clinicians and case managers and youth care workers and other support staff that we need.

Mr. COLE. Thank you very much. As I advised you, Madam Chairman, I have to step out, but I will be back. Thank you.

Ms. DELAURO. Thank you so much.

Chairman Lowey.

The CHAIRWOMAN. I too want to apologize. I am called to another hearing.

I just wanted to thank you all for your thoughtful comments, and particularly, Jonathan White, when you talked about the severity, toxicity separation of children. And I just want to read this quote again, because, as a mother of three, grandmother of eight, I can't imagine that these children who were brought here by their parents for whatever reason are being separated.

So the New York Times is saying: Since the President officially ended family separations, authorities have removed more than 900 children from their families. More than half of the children, 481,

were under the age of 10 at the time of separation; 185 of those were under the age of 5. The administration is still doing family separation under the guise that they are protecting children from their parents, even though the criminal history they are citing is either wrong or shockingly minor.

So I want to thank the chair for having this hearing again. Thank you for your good work in trying to do the right thing, but this policy is outrageous, and I do hope that we can all work together to change it. Thank you.

Thank you, Madam Chair DeLauro.

Ms. DELAURO. Thank you, Madam Chair.

Congressman Harris.

Mr. HARRIS. Thank you very much. And thank you, Madam Chair, for calling the hearing about, you know, mental healthcare.

So I need to ask—and I don't know. I guess maybe I am going to read it there. Commander White, right? Yes, it is not on there. It is on your arm. Oh, yeah, it is in small print. I am too old to read that far.

You are a licensed clinical social worker. You understand the lack of mental health professional availability in the United States. In fact, as the ranking member had said, according to, I believe it is an HHS report, the designated shortage, there are 111 million Americans who live within shortage areas, designated shortage areas. Sixty percent are in rural areas.

My district is largely a rural area. So I am going to estimate that I have tens of thousands, if not hundreds of thousands of people who live without adequate mental health coverage. Is that something that you appreciate, that there are a lot of Americans who don't have adequate mental healthcare?

Mr. WHITE. Congressman, there is no doubt that nationwide, all of the evidence that we have and everything that our Department has produced for many years affirms there is not enough mental health workforce. There are also particular deficiencies for many geographic areas.

And in the case of the children we serve, there are also additional challenges, both for those children and for anyone who needs culturally and linguistically appropriate services that those with mental health needs from Central America would have. These are national problems. They are amplified for us because these children are a Federal responsibility, but this is a giant problem.

Mr. HARRIS. Sure. But, you know, as policymakers, I mean, we always have to balance, you know, when we have a limited resource like health professionals, where are we putting them? Now, it says I guess in the IG's report that—and I guess this is true—ORR requires each facility employ at least each one mental health clinician for every 12 children in care, a ratio of 1 to 12?

Mr. HAYES. That is correct.

Mr. HARRIS. Wow. In Baltimore City, remember where there is one murder a day, where I will bet you almost every student knows someone who has been killed or some family who has had a murder a day, the ratio of counselors in schools, mental health counselors to students is 980 to 1. Twelve to 1 sounds pretty good.

I mean, is that—I mean, how are we getting to that goal? Because I don't know, you must be doing tremendous recruiting, be-

cause we can't recruit into inner cities in Maryland, where we have students who unquestionably have the need for mental healthcare, unquestionably.

So where does 12 to 1 come from? Because it seems like it is a pretty low ratio compared to the 980 to 1 that are in Baltimore City schools and the 250 to 1 which is recommended nationwide for school counselors. And, again, Baltimore City has more problems. You know, these children are exposed to trauma every day on their streets. It is a lawless environment. The President is absolutely right about Baltimore.

Where does the 12-to-1 ratio come from?

Mr. HAYES. So, Dr. Harris, the ratios of 1 to 12 for clinicians, 1 to 8 for youth care workers, and 1 to 8 for case managers is inside the ORR policies and procedures. Perhaps my colleague Commander White can speak to some of the historicity behind that, but that is specifically spelled out in our policies.

Mr. HARRIS. And you hit that ratio? I mean, you do have a 12-to-1 ratio?

Mr. HAYES. We do, yes, sir.

Mr. HARRIS. Congratulations, because it is much, much better, much, much better mental healthcare than exists in other high-risk populations, again, like Baltimore City schools' students.

There are two categories of children who are—general categories: Ones who have been separated by their parents, because they are unaccompanied children. I mean, some relative of theirs decided to send this child across a trek to sep—you can't call it self-separation, because these children had nothing to do with it. Then you have the family separation that occurred at the border under laws.

What is the ratio, what is the highest it has been and what is that now of those two, I will call them patient groups? I am a doc, patient groups.

Mr. HAYES. So, Congressman, I don't have the specific numbers. I will be happy to work with your team, you know, to get the specifics of it. But I can state, you know, the overwhelming majority of the children that are in our care, the absolute overwhelming majority are not children that we consider separated by law, meaning they came across the border either unaccompanied or with someone other than, you know, a mom, dad, or—

Mr. HARRIS. The overwhelming majority. So how do I explain to the people in my district who don't have mental healthcare that we have a 12-to-1 ratio in these facilities when the vast majority of children are there because their parents chose to separate them or their relative chose to separate them?

And I don't have—and that is a rhetorical question; you are not going to answer that. I tell you, 12-to-1 ratio is great. I congratulate you on being able to find those professionals, because we can't do it in my district.

Madam Chair, I yield back.

Ms. DELAURO. Congresswoman Roybal-Allard.

Ms. ROYBAL-ALLARD. For a long time one of the things that has troubled me is the overuse of psychotropic drugs in our foster care system. So when I read press reports indicating forced use of these drugs in ORR custody children, I found it to be extremely disturbing.

And while the OIG report showed the percentage of children in ORR custody who had been prescribed psychotropic medications was lower than in the general population, there are still 300 or more children currently prescribed medications that can have significant impacts on their psychological development without any family involvement or consent.

Ms. Maxwell, what percentage of the children reported to be taking these psychotropic medications in your report came into ORR custody already on these medications, and did your report quantify how many of the children receiving psychotropic medications were taking two or more medications?

Ms. MAXWELL. Thank you for that question. We do not have those specifics. So we were talking to their case managers and the medical coordinators that prescribe those medications, and we have the statistics about who was taking medications in care. And, as you mentioned, it was about one in 30. About 300 children in the 45 facilities we visited were on those drugs.

Ms. ROYBAL-ALLARD. Commander White, I think this is a very serious issue, particularly in terms of, you know, followup, children who are on these drugs and then are released. It can have serious consequences if they aren't monitored and either continue with the medication or are brought down from it.

Since OIG did not independently review the medical records or assess the appropriateness of the medications that were prescribed for these children, who would be the proper person or agency to go and make these reviews?

Mr. WHITE. Just a moment. I will actually defer to Mr. Hayes, as the director, because policies have evolved since I left ORR. But within ORR, there is a team of the Division of Health for Unaccompanied Children. They are career public health service officers like myself. They are board certified pediatricians, epidemiologists, pediatric psychiatrists and nurses.

And the supervisory role for the care, medical care of children and also the processes whereby children are discharged with a plan for continuity of care is ultimately their responsibility. But I will defer to Mr. Hayes to talk about the current policy.

Mr. HAYES. Yes. So Commander White answered that question accurately, ma'am. That is how I would have answered it as well. And I will just state that when I became the acting director at the very end of 2018, I delegated those medical-type decisions to our deputy director of our children's programs and her medical team as the both medical and child welfare experts.

Ms. ROYBAL-ALLARD. And so how often does that person review the medical records of these children to make sure that they are prescribing the appropriate amount, and when the children are released, that their follow-up records are also appropriately done?

Mr. HAYES. Yes, ma'am. So, Congresswoman, specific to medication prescribed, I don't have details into that. Again, that is something I would defer to the—you know, to our medical doctors on staff.

But I would say that the professionals that Commander White mentioned, that is an ongoing daily discussion across a myriad of issues with all of the medical professionals at each of our shelters,

a coordination effort back and forth with the division of health of unaccompanied children here in DC. So it is an ongoing process.

Ms. ROYBAL-ALLARD. Okay. So when a child is released, then, does that medical expert then review the record and the plan for that child when that child is released on a case-by-case basis? How does that work?

Mr. WHITE. Ma'am, particularly for minors who have higher acuity medical needs, including higher acuity behavioral health needs like you are talking about, it would be standard to have a member of that team work with the treating physician and treating medical team in the child's program on a plan for effective transition for continuity of care as the child exits the program. That is ultimately bounded by the realities of what kinds of care actually exist out in the community, which is something we don't control, but absolutely, yes, that is a very high priority for physicians on that team.

Mr. HAYES. And if I just may add, Congresswoman, you know, that could be a situation where if there is a strong medical need, that would be something where our grantee team and our project officers would work for some post-release services to identify some community-based resources to Commander White's point, again, to ensure that continuity of care.

Ms. ROYBAL-ALLARD. Okay. Does the insurance—if, say, a sponsor—they are released to a sponsor, are those medications covered by insurance? Maybe not every insurance company, but—

Mr. WHITE. So different sponsors will have different degrees of family access to the healthcare system. We in HHS do not fund ongoing access to healthcare. We are not appropriated to fund ongoing access to healthcare for discharged minors.

Minors are discharged with a supply of medication, a referral to services in the community. And part of the case management plan with the sponsor and the child is to identify how they will get those needs met in the future. But the broader healthcare system is as it is.

Ms. ROYBAL-ALLARD. Okay. And—oh, I am over. Okay. Okay. I have got plenty of questions.

Ms. DELAURO. Congressman Moolenaar.

Mr. MOOLENAAR. Thank you, Madam Chair. And, again, thank you for having this hearing.

And I want to welcome all our guests, and I want to thank you, also, for reappearing before the committee and participating in this way.

I wanted to, you know, just build on some of the discussion that has already occurred on the, you know, the health professional shortage areas. Obviously, we are concerned about people getting good access to mental health services, and, of course, these children, given what they have been through, would want to really make sure they are well served.

And, you know, the ratios that we were talking about, you know, as some of our colleagues have mentioned, it is a challenge all over the country. And my hope is that ORR has been working with colleagues in HHS to kind of look at what we are learning on a national scale and applying it to this situation as well in order to, you know, expand these resources and make the most.

One area, and just in context of my district, is in rural Michigan. We actually have 62 health performance professional shortage areas, which is pretty significant. So we are dealing with this in rural Michigan. A couple of things we are looking at is, you know, kind of innovative ways to partner with State, Federal, and local agencies to maximize the resources.

Another thing we are looking at is telemedicine and, you know, technology where, you know, people don't have to travel great distances, and you are able to—have you looked in this situation at the use of telemedicine, where it may be beneficial? Where it wouldn't be helpful? Because I am viewing that as a tremendous way of, you know, giving people the resources they need and specified treatment. But I want to get your perspective on, you know, what the potential is for that?

Mr. HAYES. So I don't have specific numbers, Congressman. But I will say that we do utilize some telemedicine practices inside some of our shelters to help, you know, meet some of the ratios that are required. So—

Mr. MOOLENAAR. And do you feel that—you know, I know it requires technology, it requires, you know, in our case, rural broadband access in every area. But what strikes me is you are talking people who speak different languages, people who have different cultural—and the idea that you could tailor that and have professionals from all over the country being available to—that could be helpful. But, you know, I don't know the limits of that.

Mr. HAYES. Well, Congressman, I just—you know, one of the things I pointed out in my testimony, and as did Ms. Maxwell, you know, one of our requirements is that you are a bilingual to be one of our grantee staff, and, obviously, have just that cultural understanding of, you know, where the children have come from as well. So that is a requirement. So that actually even further narrows the window of licensed clinicians that we have available, you know, again, having to both meet our educational standards, and experience standards, but also be bilingual.

Mr. MOOLENAAR. Are there any resources you would need to expand opportunities for telemedicine?

Mr. HAYES. You know, I am sure there could be some, sir. I don't really have any at the top of my head. I would be happy to circle back with you.

Mr. MOOLENAAR. Okay. I would be very interested in that. It is something we are dealing with in rural Michigan, and we are kind of seeing areas where it has tremendous potential, areas where it may not so much. But, you know, I think—and the other question I had, are you looking at sort of partnerships with States and local entities that could help improve the situation?

Mr. HAYES. So I would say one thing. I am going to go, you know, back to the division director of health for unaccompanied children and ask the telemedicine question, and, so, we will get back to you on that.

My goal and the goal of Assistant Secretary Johnson and Secretary Azar is to increase our permanent network capacity so that we have available permanent State-licensed beds for all the children that are referred to us from our Federal partners.

And to that end, that requires a partnership with the local and State governments, and we welcome local and State governments to partner with us in this mission to care for these very vulnerable children. And, again, we are seeing some resistance to that with certain communities, and I wish that wasn't so, because we want to be able to have, as directed by Congress and is the expressed desire of the leadership of HHS, as many State licensed permanent beds available to meet the needs of these kids without having to rely on emergency influx beds.

Mr. MOOLENAAR. Okay. Thank you very much. I yield back.

Ms. DELAURO. I am going to take the prerogative here before I introduce Congressman Pocan. I would just say that if we had a discharge plan that was adequate and move these children out quickly, as we said earlier, that the longer they are there, the more traumatized they are. It is not about building the capacity for beds. It is about building the capacity and a discharge plan to be able to get them out of the system in a safe place, as the mission has said, expeditiously as possible.

I might also add that if you want to increase professionals, increase the reimbursement rates, stop private contracting, and look at some of those issues in terms of increasing professionals, and in terms of the amount of services and the dollars where you can find opportunity for different kinds of services for the children who are there, including mental health services. We just appropriated \$2.9 billion, there ought to be room in there to be able to fund some of these efforts.

Congressman Pocan.

Mr. POCAN. Thank you, Madam Chair.

And thank you all for being here today. I appreciate it. You know, this is certainly a sad stain in our Nation's history of what has happened with this period, and we are not through it yet. So we appreciate you all being here today.

Mr. HAYES. I have a question for you. It is a yes-or-no. Do you agree that the Trump family separation policy has had a negative impact on your agency's ability to meet its legal mandate to provide mental healthcare to unaccompanied children? It's a yes-or-no.

Mr. HAYES. Could you reframe or repeat the first part of that, sir? I am sorry.

Mr. POCAN. Sure. Do you agree that the Trump family separation policy had a negative impact on your agency's ability to meet its legal mandate to provide mental healthcare to unaccompanied children?

Mr. HAYES. I agree that the separation of young children from their families created a difficult environment at the Office of Refugee Resettlement, which I stepped into in June of last year, sir.

Mr. POCAN. Yeah. I appreciate that because, you know, when we read the report—and I know you have obviously read the report—and, you know, hear things like, you know, having to go to a neighboring State for a bilingual specialist, I mean, clearly we know where these kids are coming from. Like, this should've been—it is not even a 101. It is kind of a remedial level of providing assistance to folks.

And, you know, again, it is just very sad that this happened when you hear about a 7- or 8-year-old child thinking they are

about to be killed because of this policy. You don't get much worse, I think, as far as government policy doing things like this.

Yeah, I have a question just to kind of bring it back. So we all went to Homestead, and we appreciate your time there, and since then coming to the committee. But to get back to why and some of the conditions that put children in this place, people back home still, to this day, cannot understand how we spend \$750 a day to house children for really long periods of time until we made some policy changes recently. And we had 33,000-plus kids at Homestead, when for \$750 a day you could go to Four Seasons, any Trump Hotel, which I am sure he would have enjoyed.

The fact that we finally got the children out very quickly just doesn't pass the smell test back home why it took so long. For so long, people were making a lot of money in a private facility at \$750 a day, and then suddenly we are able to move folks.

But at the very end, there were a couple hundred kids that were literally, in the middle of the night, whisked away. Can you address that couple hundred children that in the middle of the night were whisked away on the final day?

Mr. HAYES. Yes, sir. So one thing, I think you referenced a number of well over 3,000. There was a—

Mr. POCAN. Was it 2,700 or something?

Mr. HAYES. The highest number was around 2,620. I don't know the exact number.

Mr. POCAN. 2,620, Okay.

Mr. HAYES. That was the highest—I just want to clarify that.

Mr. POCAN. A pretty disgusting number, nonetheless, correct?

Mr. HAYES. Well, again, you know, it was based on the numbers of children coming across the border.

Mr. POCAN. Due to the policy that we have all agreed has put us in a pretty awkward place.

Mr. HAYES. No. These are numbers that started in January of this year, and it escalated up until June until when the referrals dropped. And the reason I am answering that way, Congressman Pocan, is because that was one of the effects on the ability to, you know, to empty out Homestead, which is the sheer drop in mid-June of referrals coming across the border.

Mr. POCAN. Well, just because one of the girls I talked to, you know, she had been there 60 days before—the week before they finally reached out to her brother. So for 50-some days, a company made a lot of money not doing their job, which was to try to place that person outside. And, again, when I tell that story back home, people can't understand it. But the 200 people whisked away, I am just trying to figure that out—

Mr. HAYES. Right.

Mr. POCAN [continuing]. Because it is something that is a question for a lot of us.

Mr. HAYES. So I asked for the percentages of kind of the last, you know, 30 to 45 days at Homestead, and—

Mr. POCAN. The last night. We are talking about the middle of the night, the last couple hundred.

Mr. HAYES. I answered that, sir. Well over 80 percent of the children that were discharged from Homestead were released to their family or sponsors.

Mr. POCAN. Right. That wasn't my question though. My question was——

Mr. HAYES. But then the ones that were transferred, the roughly 15 to 17 percent, they were transferred——

Mr. POCAN. What I am asking for really specific, please, if you could address that is, we are just wondering, a couple hundred children between like, what, 2:00 and 6:00 in the morning were taken out of the facility the last day? That is odd, right?

Mr. HAYES. No, it would not be odd, sir, for this reason——

Mr. POCAN. It is not odd. Interesting, Okay.

Mr. HAYES [continuing]. If we are going to transfer them to another shelter, which is what we did, for medical reasons or because they had no identifiable sponsor in the U.S., we would rely on commercial transportation at times, and that might involve an early morning flight if you are traveling transcontinental.

Mr. POCAN. So that was what happened to the final 200?

Mr. HAYES. Again, I don't know every single specific, but I can guarantee you, that that is most likely what happened. A lot of times our staff will escort these children on very early morning flights so that they arrive at a more appropriate time.

Mr. POCAN. Sir, just because I have got 30 seconds, is Homestead completely empty of children right now?

Mr. HAYES. It is as of August 3.

Mr. POCAN. And what are we spending to keep it empty at this point?

Mr. HAYES. I don't know the exact number, but I do know that we reduced the support capacity from the 2,700 down to just 1,200, and so, a lot of the staff were let go.

Mr. POCAN. So are we paying equivalent of 1,200 kids a day to be there, or are we just paying a maintenance? I am just trying to get an understanding of what we are spending.

Mr. HAYES. It is a fully active shelter at this time with the ability to take——

Mr. POCAN. So we are spending \$750 a day on 1,200 imaginary people?

Mr. HAYES. It is not \$750, but yes, sir, we are.

Mr. POCAN. What is the total, just so I get it?

Mr. HAYES. I think it is about \$600.

Mr. POCAN. \$600 a day——

Mr. HAYES. We are.

Mr. POCAN [continuing]. For 1,200 invisible, imaginary, non-existent human beings at Homestead right now, every single day?

Mr. HAYES. Well, it is the beds, but, yes, sir, to keep them available.

Mr. POCAN. But why 1,200 if we have no one there? Couldn't we say 100 people that aren't there?

Mr. HAYES. 100 kids or——

Mr. POCAN. Imaginary people. There is imaginary people there right now. There is no one there, but you are spending—again, I have to explain back home—even \$600 a day you are still at the Four Seasons or the Trump Hotel—why we are spending that much, but now, not to even have a child not getting mental healthcare. This is not to even have anyone stay there.

Mr. HAYES. Congressman, I think one thing you and I can agree on is that this is a very expensive program to operate. If that is the point you are trying to make, I would agree with that. I would just state that if we remove the staff at Homestead, what I was told by my planning and logistics team and the senior career professionals at ORR, you are looking at a minimum of 90 to 120 days in order to reactivate the staff back for that.

And, again, given the extreme uncertainty of referrals coming across our Nation's southern border and how many kids we might have to care for, that wasn't really a switch that we were ready to turn off at this point.

Mr. POCAN. But some of that referrals is caused by the President's policies, I would just add. My time is out, so I am sorry. Thank you.

Mr. HAYES. Thank you, sir.

Ms. DELAURO. Congresswoman Bustos.

Mrs. BUSTOS. Thank you, Chairwoman DeLauro. And thanks for holding this hearing and for the points that you have made.

Thanks to the Office of Inspector General for taking a look at this.

You know, the three of us, we are having these little side conversations up here. Congresswoman Frankel to my left, who has a grandson who is less than a year old, Congresswoman Watson Coleman, who has a grandson who is 6 years old—

Mrs. WATSON COLEMAN. Daughter.

Mrs. BUSTOS [continuing]. Granddaughter who is 6 years old.

I have got two grandkids myself, and we are all just up here listening to these words: Hopelessness, feelings of abandonment, fear, severe trauma, and we are all picturing our own grandchildren being in these situations and we are just heartbroken. And when we look at this report and every page we turn, just heartbreaking.

And I don't care who is in the White House. I don't care if it is a Democrat or Republican. And I don't care who is sitting up here, whether we are Democrats or Republican. This is just heartbreaking to listen to this.

Commander White, I was looking at your bio. You are a Ph.D. licensed clinical social worker, career officer with the U.S. Public Health Service. Have you gone to these facilities and seen what is going on there and—I am just—I want to get like this—and have you also—Ms. Maxwell, have you seen this up close and personal?

Mr. WHITE. Congresswoman, I was the senior career official over the UAC program previously. And prior to that, going back to 2012, I have been the emergency management official used in every one of the influx crises. I know these programs and their services pretty well from firsthand.

I have also been, in 2014, in the border stations, and I know what it is when we don't have bed capacity available for children in time. And that is the other part of the story that is also very important when we talk about beds not being used. And, yes, I have seen these programs and know them well.

Mrs. BUSTOS. So maybe you can talk us through, you know, when it is not a visit that has been preplanned, and as I think it was Congresswoman DeLauro was saying that, you know, you walk

in and you see smiling kids when this is a planned visit by Members of Congress. What do you see? Tell us what you are seeing.

And then my other follow-up question to that, because we get our full 5 minutes here, which is never enough time to have a decent conversation about all this, what are the long-term consequences of the kids who are living through the severe trauma, the angry feelings, the anxiousness? What are we going to see when these children are teenagers, and what are we going to see in our society as a result of what the government has done to these children?

Mr. WHITE. So what you see when you are in a program on a regular day without Members of the United States Congress there is not, in my experience, very different from what you see on a tour except that the staff are much more nervous when there are Members of Congress there.

The children that you see and the environments in which you encounter them are what you would also see in domestic congregate child welfare settings licensed by the State because, that is what they are.

The children, as you talk to them and work with them, represent a range of experiences. Many of them have sustained extraordinary—extraordinary histories of trauma in home country, in transit, and, in some cases, in the United States.

Separated children are intrinsically different, however, in that the traumas they have sustained are both extraordinarily severe and they are currently ongoing. And we are part of that traumatization in the United States Government, which is different than being the response to that traumatization.

Long term, the consequences of separation, for many of these children, will be lifelong. It will involve both behavioral and physical health harm that all the best available evidence we have on trauma and toxic stress, including that that focuses on children separated from their parents, would suggest will be both severe and very difficult to manage, even with high levels of clinical care.

Mrs. BUSTOS. And all this could be prevented if the United States Government in this administration, didn't have these kind of policies that is allowing these children to go through this kind of trauma?

Mr. WHITE. Separation, other than for strict cause, is preventable. However, Congress has not passed legislation of any kind to define the conditions under which separation may occur. And as I have asked previous committees, I will say again, that is a gap in law, and it is one that this Congress could, and, I would submit, should address.

Mrs. BUSTOS. Okay. I am down to 3 seconds, so thank you for those answers. Appreciate it. I yield back.

Ms. DELAURO. Congresswoman Frankel.

Ms. FRANKEL. Thank you. Okay. My little sponge here fell off. Okay.

Mr. WHITE. We can hear you, ma'am.

Ms. FRANKEL. You can hear me? Okay.

Thank you all for being here really. And, you know, I really can tell from your expressions and what you are saying that all of you are very sincere about trying to correct the very terrible situation, which I know none of you really caused.

But I just want to echo, before I ask my questions, what my colleague here, Mrs. Bustos said, because, right, you know, I am a new grandmother. And when I just think of the brutal, cruel policy of taking children from their parents, and to me, this is just government child abuse. It is child abuse.

I want to start, because I want to emphasize what Representative DeLauro has been talking about, which is the agreement with HHS where HHS has agreed to share personal information of potential sponsors with agencies that can actually go to a home and, perhaps, take a—seize an undocumented citizen.

And I think what we experienced when we were at the Homestead—we all went to the Homestead facility, is that one of the feelings that we got is that—one of the big reasons for the delay in getting these children back with any member of their family was because of the fear, the fear that by giving an enforcement agency the ability to go to a home and then pick up an undocumented citizen.

So, Mr. Hayes, I just want to know whether or not—what, if anything, are you doing about trying to get this agreement rescinded?

Mr. HAYES. So I just would say one thing, actually to correct Commander White. I don't believe the staff at the facility in your district was scared of you. I think they actually looked forward to you coming to the shelter, ma'am

Ms. FRANKEL. I agree. I agree.

Mr. HAYES. They even had your picture up on the wall, so—

You know, I think one thing is clear. I think there is some confusion around the information that is shared. I think it is important—I noted this on the tour at Homestead and as well at my last testimony here, is that going back to 2004, every time a UAC is discharged from ORR, they then go to the jurisdiction of the Department of Homeland Security and that discharge notification form does go to DHS with the sponsor's information and the child, because it then, you know, falls on DHS and Department of Justice to keep them apprised of their court proceedings. So I just think that that is—

Ms. FRANKEL. No, I understand. But look, because I have some more questions.

Mr. HAYES. Yes, ma'am.

Ms. FRANKEL. Look, here is the point we are trying to make is that that process is keeping children and families separated.

Next question—

Mr. HAYES. May I—

Ms. FRANKEL. Can I—

Mr. HAYES. Yes, ma'am.

Ms. FRANKEL. Well, I want to ask another question. There is a new policy, I understand, that the President has put in place that now prohibits people seeking asylum to come into the country so they get stuck in Mexico. Is that correct? Is that going to affect the number of the undocumented children coming into the country?

Mr. HAYES. I think the impact is unknown. There are a couple of things that are ongoing with some of the asylum laws, and, again, HHS is not an immigration enforcement agency. I know we did issue a Dear Colleague letter where certain components of that we don't believe will impact the, you know, folks that are eligible

to come into ORR care, both on the refugee resettlement side and—

Ms. FRANKEL. But they have to come into the country first, right? Is it going to be hard—the reason I ask this question is because Mr. Pocan asked about spending a lot of money on invisible people. I am just wondering, are you actually expecting more undocumented individuals to get in here, given the new policy?

Mr. HAYES. Right. Yeah. While I will acknowledge that the chairwoman is correct, our referrals number are low. But if historical trends—and I would yield to Commander White here in a second as well, but if historical trends hold true, the expectation should be that as we move into these cooler months, there is a pretty significant chance that the referrals will increase, and most certainly as we get further into November and December, an even greater chance.

Commander White.

Mr. WHITE. I did just want to say this, and I will keep this brief out of respect for you, ma'am. Every influx crisis in the history of this program—and in fairness, I have been deeply involved in response to all of them. So I have some experience to speak from. Every one of them was preceded by a period of reduced referral and pressure to reduce capacity or stop expanding capacity.

And I have asked colleagues on the career side, on the appointed side, and I will now ask Congress, can we please not make this mistake again of thinking that every time it goes down that that is, like, the future. This is an oscillating, highly volatile system, and the best way to keep children out of the—off the floors of border stations is to not react when there is a downturn and say, Oh, look, that is the end of migration highs.

Ms. FRANKEL. Let me just say two points that I guess—because I am running out of time here. But one thing that we found on our visit is that children who were reaching the age—they were getting to an age where—

Mr. HAYES. Age out.

Ms. FRANKEL [continuing]. They were going to age out—

Mr. HAYES. Yes, ma'am.

Ms. FRANKEL [continuing]. A terrible stress on them because that meant they were going to be incarcerated.

And the second thing is, I think what we have to remember that these children, once they are released or to a family or whatever, you know, a lot of damage has been done and now they are out in our community. And my question is, is there follow up? Do they get mental health services, or is that it?

Mr. HAYES. Yeah. So whenever a child is discharged—two separate questions, ma'am. So we do have children that do age out. Once you turn 18, the statutory authority at HHS ends inside the ORR UAC program. Our teams work very closely with the local ICE officials to come up with a post-18 plan. And as I said on the tour, if it were solely up to our grantees and the ORR career staff, the kids could stay with us until they were 22, but it is not our decision.

Ms. FRANKEL. No. No. They are going to—

Mr. HAYES. We do work very closely, and a lot of times they are released in that post-18 plan on their own recognizance. I would

just add, as far as the second—what was the second question you asked?

Ms. FRANKEL. What happens once they are released? They have this trauma. Yeah.

Mr. HAYES. So there is a 30-day follow-up call from our team, and if there are post-release services that are recommended by the team, again, we work with a particular project officer at ORR with approximately 11 grantees to identify post-release services that might be available within the community.

Ms. FRANKEL. Thank you.

Ms. DELAURO. Congresswoman Watson Coleman.

Mrs. WATSON COLEMAN. Thank you very much. Thank you for being here.

And, Madam Chair and Ranking Member, thank you for hosting us here in this very important committee meeting.

Before I start asking my questions, I need to make a comment. There was a comment made up here by one of my colleagues, and it had to do with—I found very offensive. And what it suggested was that parents are making a choice to be separated from their children, and I just cannot believe that that is the truth in any way, shape, or form.

I am a grandmother, and I am sitting up here listening to what these young children are going through. My granddaughter is 6 years old, and it breaks my heart. Not only does it break my heart for the child, it breaks my heart for the parent or the relative of that child. And I just think that we are in the wrong—we are moving in the wrong direction here.

Do we or do we not have a no-separation family separation policy now? Let me ask you, Mr. Hayes.

Mr. HAYES. So—

Mrs. WATSON COLEMAN. Is that a yes or a no?

Mr. HAYES. Yeah. So based on my understanding, the President did issue an executive order stopping family separation as a result of the zero-tolerance policy specifically for an immigration violation. However, separations do continue for other reasons and have—

Mrs. WATSON COLEMAN. Such as?

Mr. HAYES. Such as past criminal activity of the parent, legitimate child welfare concerns. There is a myriad of issues. I would be happy to get you a list of the different categories that fit into that. But I think it is important to note that there have been separations in the entire history of this program.

Mrs. WATSON COLEMAN. So you were very successful in reducing the census at your facilities extremely.

Mr. HAYES. Yes, ma'am.

Mrs. WATSON COLEMAN. And I would like to know specifically what were some of the things that you did to facilitate that release, and are those things part of an ongoing policy now?

Mr. HAYES. They are, ma'am. I issued four operational directives, so the first one, about 3 weeks after I was named the acting director at the end of November. The first operational directive ended the household member fingerprint checks, which the counsel of my senior career staff and child welfare experts did not deliver any new or additional information that would cause them to change the decision to discharge that child to his or her family member.

The second operational directive was in March of this year, ma'am, and that was in regard to the moms and dads that are seeking to sponsor their children. We quit fingerprinting them as well, provided there was no red flag or hit on the public records check or sex offender registry check in that.

The operational directive number three had to do with the immigration status checks. We suspended the reconciliation of the ICE background checks, results from our sponsors. We rely on the testimony and communication with each sponsor. The only thing we ask is that if a potential sponsor is undocumented and here without status and could potentially be deported, is there a safety plan, meaning who will the child go to if you are deported?

And then the fourth operational directive was also done in June of this year where we are—still to this time, but it is a temporary action—we are treating the grandparents and adult siblings the same way we would moms and dads, meaning if they are seeking to sponsor the family member and there are no hits or red flags on the public records check or the sex offender registry checks, we do not do the FBI fingerprint checks which does take additional time.

Mrs. WATSON COLEMAN. So during—

Mr. HAYES. And I will just add, I visited over 50 of our shelters, and that was one of the recommendations that came from the field that I brought back and discussed with the team and we implemented.

Mrs. WATSON COLEMAN. So during that period of time, where you were you able to facilitate those releases more quickly—

Mr. HAYES. Yes, ma'am.

Mrs. WATSON COLEMAN [continuing]. Did they suspend looking at everyone that lived in the household, determining what their status was?

Mr. HAYES. We still do the public records check, but again—

Mrs. WATSON COLEMAN. What does that mean?

Mr. HAYES. It like, you know, looks at both the Federal, the State, law enforcement-type background to see if there is any hits or red flags or anything to give us any kind of concern.

I will point out that at the end of the day it is about the integrity of the sponsor.

Mrs. WATSON COLEMAN. Yeah, I agree.

Mr. HAYES. They can only tell who is in the house and who can move the next week. So that is where I want my team to focus, on the sponsor.

Mrs. WATSON COLEMAN. So, you know, I know you are not the cause of these policies. You are the recipient of these policies. So this memorandum of agreement, or understanding, really doesn't need to exist. And do you have the authority or does your department have the authority to withdraw from that agreement? And if so, why haven't you?

Mr. HAYES. I do not have the authority myself. I am not going to speak for the Department of Health and Human Services.

Mrs. WATSON COLEMAN. But you are the frontline person. Do you agree that we can function without that, if we had the safeguards in place that were used to facilitate the release of those children?

Mr. HAYES. I would just say, I think the actions I have taken since becoming acting director and director speak to my overall belief of the majority of the MOA. I just will flag though that, you know, there is referral information, information learned by DHS after the child comes into our care. It kind of memorializes the—also the abuse reporting to DHS when we learn about it. So there are some things left in the MOA.

Mrs. WATSON COLEMAN. Thank you.

Mr. HAYES. But in regard to your processing the children—

Mrs. WATSON COLEMAN. And, Ms. Maxwell, do you agree that this MOA could be suspended?

Ms. MAXWELL. We recommend that ORR do what it is continuing to do which is to assess all of their current policies to make sure there are no unintended consequences for releasing children. So we would recommend a continued reassessment.

Mrs. WATSON COLEMAN. Thank you. I yield back. Thank you.

Ms. DELAURO. Congresswoman Lee.

Ms. LEE. Thank you very much, Madam Chairman. Thank you and our ranking member for this hearing. And it is a very troubling hearing for me personally, and as I am an elected official.

First of all, I have to remind you—and in making this statement, I want to be very clear that we recognize that this is the 400th year since the first enslaved Africans were brought to America. One of the basic elements of the United States policy was to take children from their families. That was family separation. This has had generational impact. We are still addressing it and dealing with the trauma today.

This is yet another stain, another stain on our country. And I am not personalizing it toward any of you, because I know what you are feeling and what you are seeing. But I want to put this in context so we understand what is taking place. This policy did not just start.

I am very concerned that a lot of the recommendations that the American Psychiatric Association—and I want to read some of their testimony to this committee—and also the National—or American Society of Pediatrics. I am not sure if that is the correct name of their group, but I want to explain a couple of recommendations they made.

First of all, they said that we needed an independent medical and mental health monitoring team, totally independent from the government. Secondly, the psychiatric association—let me just read you a couple of paragraphs from their statement.

“We know that children are more susceptible to trauma because their brain is still developing. When a person is exposed to a traumatic event, the brain naturally enters a heightened state of stress, and fear-related hormones are released. And although stress is a common element of life, when a child is exposed to chronic trauma or extreme stress their underdeveloped brain will remain in this elevated state.

“Ultimately, consistent exposure to this heightened stress or trauma can change the emotional, behavioral, and cognitive functioning of the child in order to promote survival.

“Psychiatrists are most qualified to help children and family recover from the trauma inflicted upon immigrants and refugees by

displacement from and within their home countries and can provide direct psychotherapeutic and psychosocial intervention. Each staff and their leadership teams should really address the appropriate care suffering and identify this as posttraumatic symptoms and other migration-related symptoms of distress.”

And then they go onto explain—one more thing I would like to read from their testimony: “Detention of innocent children should never occur in a civilized society, especially if there are less restrictive options because the risk of harm to children simply cannot be justified.”

Now, I want to find out from you what in the world happens to these children after this damage has been done by the policies that this government has put in place in terms of trauma-informed mental healthcare?

I recognize the mental healthcare has—I am a psychiatric social by profession. There are a variety of treatment modalities. But these children require specific trauma-related treatment, and it is not one, two, three, four, five, six, seven sessions. This is years of treatment they are going to need.

So how are you going to do this? And what type of resources—have you met with and talked with the professionals on the outside who could probably give you a lot of help in what you are doing?

Mr. HAYES. Thank you, Congresswoman.

I would just, you know, point out that I—and, again—thank you again for the, you know, for the supplemental funding that you all provided. I know a part of that was not less than \$100 million to increase both legal services, post-release services, and child advocates, and that is something that we are working on with our grantees.

We have recently sent out a request for proposal to expand those post-release services available to the children, especially those that need long-term mental healthcare and behavioral health issues as they leave ORR care.

Ms. LEE. Are you specifically saying trauma-related care related to PTSD?

Mr. HAYES. I don’t know how specific we are getting. It is a broad array of post-release services. It could be medical care, legal services, educational, school—

Ms. LEE. I understand that, but I am focusing on the mental healthcare right now, in terms of the appropriate types of mental health treatment modalities that you are going to use to make sure that these kids don’t end up, when they are adults, not very happy with our own country.

Mr. HAYES. Right. Do you want to speak to that, sir?

Mr. WHITE. Ma’am, that is a focus of the efforts. And as you know, among the challenges are the delivery of appropriately intensive psychotherapeutic services during the duration of time the children are in care. So the answer to your question is absolutely.

One of the key focuses for the current efforts to further strengthen our ability to deliver appropriate trauma-informed services to children in our care is to work with experts, including NCTSN, to identify what are the best evidence-based methods to respond to the very high—both the high ACEs scores, the history of toxic stress, and the traumatic exposures that children have during the

window of time that we have and with the resource picture we have. So the answer to your question, Congresswoman, absolutely.

Ms. DELAURO. Congresswoman Clark.

Ms. LEE. Time is up, okay.

Ms. CLARK. Thank you, Madam Chairwoman.

Thank you, all. We appreciate you coming back, and for our new arrivals, your testimony here today.

It is hard to know where to start. Commander, as you said in response to some previous questions, the only real way to address this level of trauma in children is prevention. And we know that many of these children are coming to this country already experiencing great trauma, where they lived at home, in transit. But we have added to this.

And I want to reiterate what my colleague, Congresswoman Lee said. We know that you are trying to do jobs in a tough and changing situation. But I think you have to understand how it looks from our vantage point, that children are being used in this immigration policy, and the harm that we are inflicting on them and on these families may be irreparable, and that we have a role in that as the U.S. Government.

And what troubles me deeply about Homestead is that this is a private contract with Caliburn International, where Secretary John Kelly sits on the board. And they wrote in their filings for the SEC as they announce plans to go public, "Border enforcement and immigration policy is driving significant growth for our company," significant growth. At what cost to the human experience and to this stain on our country in the way we are treating these immigrant children?

And to hear that we continue to pay—and I understand very clearly that we need to understand that these—that migrant patterns are patterns, and they go up and down and we want to be ready. But there are other programs out there that exist like the case management, that I understand is, you know—homeland security program not under your purview. But it works. And it has great compliance with families getting to court, to making sure their asylum cases are heard, have a fair decision. And what does it cost? It costs \$36 a day.

These are the type of programs that I would think that when we are experiencing a decline in population, why aren't we looking at those type of programs that get kids out of detention and with their families and have compliance? Why aren't we looking at increasing our nonprofits that can save money instead of continuing to operate Homestead empty at almost double the rate of what we pay some other agencies to take care of children. These are big questions, but if you could give me some direction, Mr. Hayes, I would appreciate it.

Mr. HAYES. Yes, ma'am, Congresswoman.

So I think I just would point out that, again, the Homestead site and the operator was chosen back in late 2015, long before General John Kelly joined any of the companies that you mentioned. Yes, we did renew that contract with them.

I would just say that—again, I want to reiterate my statements earlier—I am absolutely committed to, as is Assistant Secretary Johnson and Secretary Azar, to having as many State-licensed per-

manent network beds as possible to receive these children. And we are working to that end.

But the challenge that we have, Congresswoman, is that at the end of the day, the final say in those facilities being licensed and receiving children does not lie with the Federal Government. It requires a partnership with the States and the local communities.

And we are, again, starting to see some resistance to that, and that is very unfortunate. I would respectfully request this committee to help out and help us—as, you know, one of the stakeholders in this process of caring for these children—help us achieve that goal of expanding the type of shelters that we have in Ms. Frankel's district that she and I went through. It is about 140 beds for teenage girls, and it is a wonderful facility. That is what we want, and we are working towards that.

But to Commander White's point, when we see huge influxes of children coming across the border, and the need to be able to secure them, you know, we have to be able to, you know, have those beds available. And if we are having challenges—

Ms. CLARK. Mr. Hayes, are you working at all to redefine what we mean by family members? When I was at Homestead, we heard many stories of children coming across the border with grandparents—

Mr. HAYES. Ah, yes.

Ms. CLARK [continuing]. Who did not qualify and made these children unaccompanied minors. If we are trying to reduce trauma to children, if we are trying to keep children out of detention beds, not be separated, are you working actively to say why don't we include aunts and uncles and grandparents in a definition of family that is rational?

Mr. HAYES. So that is not my decision. That authority lies with Congress. And I know that the senior staff that I speak to would absolutely support some modifications to the Trafficking Victims Protection Reauthorization and the Homeland Security Act that drives that.

Mr. WHITE. The definition of children who cross the border with a loving grandparent, with abuelita, with an older brother who is over 18, to define those children as unaccompanied is a Black Letter law issue.

Congress absolutely has the power to make that change, if you wish. But neither DHS nor HHS has any legal authority to consider a child who crossed, even with a loving grandparent, even with a loving older sister, as anyone other than unaccompanied. That is not our call.

Mr. HAYES. Right.

Ms. CLARK. It is not your call, but would you support that change?

Mr. WHITE. I would support that change.

Ms. CLARK. Would you, Mr. Hayes?

Mr. HAYES. I would as well, and I have heard it from a number of my staff. And I just want to point—I believe that is what is at the heart of my fourth operational directive in late June, where we are at this time, when it comes to the background check process of the sponsor discharge package, we are treating grandparents and adult siblings the same way we would moms and dads, because

as a father of five, I completely agree. I want these kids with family members as they wait for their court proceedings to go forward. Anything I can do that make that faster while still holding up an acceptable level of safety, I will do that in conjunction with collaboration of my team.

Ms. CLARK. Thank you.

Mr. HAYES. Yes, ma'am.

Ms. DELAURO. You can be sure that we will address that issue and that there will be legislation as quickly as possible. And I am hopeful that my colleagues on both sides of the aisle would be in agreement since you are all in support of it.

The other piece is, I might add, that Assistant Secretary Johnson at our hearing, who with all due respect, Mr. Hayes, is, I think, your boss, if you will—

Mr. HAYES. Yes, ma'am, she is.

Ms. DELAURO [continuing]. That she said that we should rescind the memorandum of agreement. So I am hoping that we can, or that the assistant secretary will be listened to by the administration of doing that. That is why you put good, solid, bright people like the people who are here this morning, who understand these issues, and make recommendations about what we should do.

I am going to get to my questions but I have got to say, the issue is discharge, discharge, discharge. Focus is always on holding the influx facility and the numbers are going down. Yes, they can go up. However—however, with a change in one directive, in 2018, in December, we went from—and you pointed out that I was inaccurate—I said overnight 15,000 kids. We let 4,000 out. You told me, Mr. Hayes, it was 8,000.

So if we can move kids that fast, we do not have to have them sleeping on the floor at a DHS facility, which no one wants them to do that. But we were able to move, we moved quickly, and we are now down to, as I understand it, some 5,800 kids. We did not have to have a backlog. We did not. That was created.

And you have got the \$2.9 billion, and now, you are less engaged in dealing with \$750 a night for a facility, which was the reason why we had to build the capacity, build the capacity, build the capacity. And what we need to do now—and I want to see that plan in October of how we move kids out as fast as we can to a safe—a safe placement as expeditiously as possible. That is your goal. I don't speak for DHS. I don't know what their goals are. But that is HHS, which is under the jurisdiction of this committee.

Mr. Hayes, you talked about the webinar series, okay. And I am proud and excited, and the ranking member understands this, the National Child Traumatic Stress Network—I will be self-serving for the moment—I was the first Member of Congress to put funding into that system, because I understood what it did, as my understanding of it through the Yale Child Study program in New Haven, Connecticut. And we helped to craft that and provide money for it. So we have done that. I am glad you are there.

You have talked about—I want to hear about the direct services. You talked—other than the webinar series. What have you done to increase access of child trauma experts to children in HHS facilities, while children are in ORR care, and in the post-release situations? As I said, you have got \$2.9 billion. Numbers are down. We

don't have to pay the \$750 a night. How are we rearranging those dollars to assist in this process?

Mrs. WATSON COLEMAN. We are still paying \$600 a night.

Ms. DELAURO. We are paying \$600 a night. Yeah. So \$750 to \$600. \$150 a night, that is real money. I believe that.

Mr. HAYES. It is, yes, ma'am.

Ms. DELAURO. Yeah. Talk to me about direct services.

Mr. HAYES. I just want to point out for the record, too, none of our grantees makes the decision on any child going to their shelter. That decision is made by Federal staff on the intakes team at ORR. So, I just want to make sure that people understand that whether it be Homestead or whether it be, you know, a BCFS facility in the Rio Grande Valley, that is not a decision that any of the grantees make. Federal staff provide oversight and make the decisions on where the children go.

In regards to the children that are in our care, Madam Chair, I just would again point to, you know, to the OIG's report and to the counsel—

Ms. DELAURO. What direct services besides a webinar are you going to? Please, because, you know, they are going to kill me if I am going overtime.

Mr. HAYES. I understand. Given the very short time that these children are in our care, the focus of the clinical work of our team is to focus on both providing a safe and secure environment in stabilizing the child. Again, that is right out of the OIG report, and the report that you showed, you know, the length of care significantly dropping.

And I do know that I always want to be the type of director that listens to the counsel of our medical team. And I have heard it firsthand out in the field, and also here in DC, that, you know, there is a hesitation to really get into some of the deeper trauma given the fact they don't know how long they are going to be in our care.

Ms. DELAURO. But, you know, you need to deal with direct services. Are you going to take any of this money from the \$2.9 billion and provide it there? Because you say you are going to add your own funds to what is going on at the NCTSI.

Mr. HAYES. We will continue to seek ways to properly invest that money in the care of the children, yes, ma'am.

Ms. DELAURO. Okay. I will come back to additional questions. Congressman Cole.

Mr. COLE. Thank you very much.

A point I want to make and then a couple of questions to ask, the point is—and you were, I think, there, Director Hayes, when we were down along the border—there is a lot of manipulation of these unaccompanied minors by people coming into the country.

We were told that, literally, only 1 percent of adult males in 2015 that were coming across that border had an unaccompanied child with them, and it is 50 percent now. So there is clearly, you know—some of these kids are being used by adults that think it enhances their chances of being—of getting in the country and being able to stay. I don't know how you deal with that, but it is something we ought to recognize that they are having to confront down there.

It was very interesting to see. And, again, the money Congress voted gave them the capability. We are doing DNA tests on selected individuals just to see if the people were related. About one out three of the people they tested were not related in the manner described.

So this is—you know, these children have been used, literally, in these kinds of cases by people trying to get into the country illegally and by cartels, and that is just a fact. And you are confronted and we asked you to deal with it and you don't do the apprehensions. You just—you know, you are dealing with the kids that we turn over to you.

Question I have, and there is a tension here—and I know we are all trying to get to the right point, but a tension between getting them placed as quickly as possible, and giving them the best care that we can give them after a very traumatic experience, because you don't have them there, as the commander pointed out, very long, and as you have pointed out.

So could you describe a little bit how you handle that dilemma and what, you know—in what ways, if any, does the care follow the child or—you might not even have had time to actually assess the full needs of the child in the amount of time that you have them there. So this is a real problem area, I think.

Mr. HAYES. Thank you, Congressman. To your point, I know of a recent example where a child was in our care for 3 or 4 days before she was discharged to her mother. It was not a separation. And so, if there is circumstances surrounding what happened back in home country, the journey, and then coming into our care, I mean, she was only with our shelter for maybe 3½ days before where I think is a more appropriate environment, she moved with her mom.

So, that is a question, that I would not seek to answer. I am not a mental health clinician. But, again, I receive counsel from a large number of them, and their focus, again, not knowing exactly how long the children are going to be in our care, they focus on stabilizing the child and making sure that the child feels secure, because I think, to a point earlier, they do view initially, at least all of us, as kind of the same bucket in regards to the U.S. Government.

But we see that as they spend more time in an HHS shelter, and it is like not in detention and they are surrounded by medical professionals and clinicians and youth care workers and other kids, you know, their comfort level and their confidence in our team, you know, does absolutely increase, and we learn more about the child and his or her journey and their history. And as that stuff is told to them then that is incorporated into the clinical work that our team does.

But, again, to the OIG report's point, you know, it is tough when you really don't know how long you are going to have that child and the licensed mental health professionals tell us that there is a hesitation to want to try to get into that too deep, if they might be gone within a week or two.

Mr. COLE. Commander, if I could, I would like your thoughts on this. You know, in terms of—again, we obviously want to place them as quickly as we can in an appropriate environment. How do

we make sure—and again, these kids have been traumatized before they get here in many cases, either by conditions at home or the journey, you know.

What are your thoughts on how we make sure that while we are placing them rapidly, you know, we can both diagnose the problem and see if there is something that we can do about it? I mean, they move out of HHS's care pretty rapidly, and that has got to be a challenge in this area.

Mr. WHITE. Yes, sir. There are three things we have to do, and I want to be really clear, both as a person who has managed this program and as a clinician, they are hard. They are hard, but they are necessary.

The first thing we have to do is we have to build every one of our programs from a trauma-informed lens, so that not just the minute that the child is sitting with his or her clinician, but every moment that they are in the program we are doing what we can to mitigate the traumatic experiences they have sustained, as well as the distress of the time that they spend in congregate care.

The second thing that we have to do, is we have to provide both individual and group modality psychotherapeutic interventions to every child. These are not a random cross-section of children.

The life experiences of children, particularly for the more than 90 percent of the children in the ORR program who come from the Northern Triangle of Central America, these are children literally coming from the worst places on Earth to be a child, where the vast majority of these children have observed homicides, have experienced personal traumatic loss, have been victimized themselves through physical assaults and sexual assaults. That is not uncommon in this program. That is the norm. So the second is we need to have those methods in place, recognizing all of the incredible challenges to doing that.

And the third is that we need to continue to work as we do, with sponsors, to identify the resources that they can access individually in the communities where they live to provide continuing care for the children. I want to be really clear, all of these things are incredibly hard. And that is why the guidance from OIG matters. We are not failing at an easy thing. We are continuing to struggle at an incredibly difficult thing, and I am very proud of what my colleagues in ORR do every day on this problem.

Mr. COLE. Thank you very much.

Thank you, Madam Chair.

Ms. DELAURO. Thank you.

I would just say just to follow up quickly on something that Congressman Cole said, which is—and I think you have made reference to it, Commander, is the post-release services. And we know, I think we all know that there is a serious, serious backlog, and that there are children on this wait list, thousands of kids flagged to receive services waiting weeks or months before they receive the kinds of services.

So I am going to yield to Congresswoman Roybal-Allard, but if we come back again, I really would like to pursue post-release services and that backlog.

Congresswoman Roybal-Allard.

Ms. ROYBAL-ALLARD. Before I ask my question, I am a little concerned, as was Mrs. Watson, that an impression may have been left that somehow parents are just sending their kids here, picking and choosing and sending their kids here. And, you know, we have heard from the immigrants that we have spoken to as to the various reasons, which we have all heard, rape, gangs, and so forth.

I was on the trip to the Northern Triangle with Speaker Pelosi, and the reason we went there was to hear from our own government agencies, the NGOs, USAID, the Coast Guard, CBP, the agencies that are there on the ground, as to what their thinking was, and the reasons why so many young people and parents were coming to the United States.

And they validated everything that we had been told by the immigrants themselves as to why they were coming. In fact, in some cases, what we learned was even more horrific. For example, USAID was saying, and some of the other agencies were saying that they were now focusing on the 8- to 12-year-old kids, and using the money, or the foreign aid that we are sending there to focus on the 8- to 12-year-old kids, because that is where the gangs were focused, on recruiting the 8- to 12-. And if these kids didn't join, they would then threaten them with killing their parents or a sibling. And to be part of that gang, the 8- to 12-year-olds had to kill five people. That was the price. That is why parents are sending their children here.

Also, when I went to Texas with Congresswoman Escobar, we crossed over to where there was one of the shelters on the Mexican side, and there were about 80 or more immigrants there from different countries. The Congresswoman asked them why they were there. We heard similar things, including the fact that they could no longer grow crops in their country, and they were hungry. They couldn't feed their families and were coming to the United States.

She then asked them, if you could provide for your family, and if you could feel safe in your country, how many of you would still want to come to the United States? Not one person raised their hand. They said, No, we love our country, we want to be in our country. We are here because we had no choice. So I just want to make it clear that parents are just not deciding for the heck of it to send their kids to the United States.

Ms. Maxwell, according to your report, even mental health clinicians with prior experience in this field felt unprepared to handle the level of trauma that these children had experienced. If the trained mental health providers felt unprepared, I would assume that ORR caretaking staff must be completely overwhelmed when faced with the needs of these children. And I understand that your investigators spoke with the mental health and physical health clinicians during the investigation, but did your investigators speak directly with the caretaking staff about their training on how to meet the mental health needs of these fairly traumatized children who were under their care?

Ms. MAXWELL. Thank you for that question. We have a broad body of work that we are undertaking, and we asked a whole host of questions. We did talk to the youth care workers. That is for a future study that is coming out later this fall. In this particular study, we focused only on the mental health clinicians.

Ms. ROYBAL-ALLARD. So do you know when that study will be coming out?

Ms. MAXWELL. As soon as we can get it through our very rigorous quality control process, we will have it in your hands.

Ms. ROYBAL-ALLARD. Do I have time for one more? According to the Flores settlement agreement, each child in our custody should have a comprehensive and individualized plan for care. Did your investigators check to see if there were care plans in place for these sexually traumatized children?

Ms. MAXWELL. Not in this particular study. We have an ongoing series of audits that looks at eight grantees over six different States. In those particular audits, we did look at whether or not grantees were compliant with rules and regulations, and one of the regulations we looked at was whether they had care plans. In some cases, we did find documentation missing in children's files.

Ms. ROYBAL-ALLARD. Okay. So a lot of the issues that we are bringing up then will be in subsequent studies. Am I—

Ms. MAXWELL. The audits that I am talking about, a number of them are already public. I will be happy to share them with you so you can see specifically what is happening at various grantees. The study I was referring to looks at the safety in the facilities, and that will be coming out later this fall.

Ms. ROYBAL-ALLARD. Okay, thank you. I see my time is up.

Ms. DELAURO. Congressman Harris.

Mr. HARRIS. Thank you very much, Madam Chair.

Let me just clear it up for the Congress ladies who had a question about it. I just reiterated, I think, Mr. Hayes, that you said the vast majority of children you are taking care of now are UACs, not people separated by legal policy. Is that correct?

Mr. HAYES. That is correct.

Mr. HARRIS. Okay. So to say that the Trump administration is somehow responsible because of the pitiful conditions in the Northern Triangle that make a parent choose to separate themselves from their child is not this Trump administration, neither is it the Obama administration or any of our policies. It is a problem in those home countries.

The Northern Triangle, let's talk a little about the Northern Triangle. Let's get back to Baltimore, or Detroit, and New Orleans, all of which have a murder rate that is higher than Guatemala. Baltimore's is on level with Honduras. El Salvador does take the cake, all right, they are higher.

So, again, I would just offer that we have a public health issue in this country with taking care of the mental health of children who are exposed, and the failure, the failure to control the murder rates in large American cities that certainly the Trump administration doesn't control.

All right. Let's talk a little about the fingerprinting. Under your policy, do you fingerprint fewer people or more categories of people than the Obama administration fingerprinted when they released? My understanding, for instance, is you don't fingerprint grandparents—

Mr. HAYES. Right.

Mr. HARRIS [continuing]. Who have taken care of children, when the Obama administration did fingerprint grandparents.

Mr. HAYES. At this moment, we are fingerprinting less, because we are not doing grandparents and adult siblings.

Mr. HARRIS. Less. Well, that is interesting, because I certainly didn't hear that as a compliment from anyone saying, Oh, by the way, congratulations, you are actually doing less fingerprinting; therefore, resulting in less fear of family unification than under the last administration. So I thank you for doing that, okay? No question about it.

Now, let me just get to the crux of how separation occurs, because if you are a parent with your child, you are a single mother with your child and you go to a port of entry, and go through the legal process of filing for asylum, you don't end up in ORR. The child doesn't end up in ORR custody unless there is some question about the ability of the—the qualifications of that parent to be an adequate parent, they are not a criminal, et cetera. Is that right?

You are only taking care of children whose parents broke the law, right? Because you don't break the law. If you request asylum in a port of entry, you don't break the law and there is no question of separation unless, of course, you are a criminal yourself, the parent is a criminal. Is that correct?

The children in your custody, in fact, are not children whose parents have followed the asylum law of the United States by entering through a port of entry?

Mr. HAYES. I think I just would want to qualify, Congressman, that the majority of children in the care of HHS did not come across the border with a mom or a dad.

Mr. HARRIS. Yes. Oh, I fully get that. But now, I am talking about whether this administration is responsible for the parent breaking the law and not following—because my point is, if the parent followed the law—and we know the vast majority request asylum. I mean, that is not your bailiwick, but the vast majority of people crossing the border now request asylum.

If they request asylum at a port of entry, following our asylum law, there is no question of automatic separation, and there never was. Is that right? And, again, maybe I should be asking DHS.

Mr. WHITE. Unfortunately, Congressman, among the separated children in the Ms. L. class, including the named plaintiff, there are children whose parents presented at a U.S. port of entry. Nonetheless, I think the take-home is that the vast majority of children in the care of ORR are truly unaccompanied, not separated children.

Mr. HARRIS. That is correct. And, in fact, their parents broke the law. So one solution, prophylactic solution, I guess would be, to enforce border law. Maybe if we actually enforced the law, we would not allow people to enter illegally with their children, which has resulted in separation. I am not going to judge, but is that more or less correct? I mean, we really are—and I am going to have to look at those cases. My understanding of the law is if you enter—you are legally present in the United States, if you entered a port of entry, requesting asylum, so doing everything you need to do at a port of entry. But I will check on that.

Again, if we just enforce border law, we wouldn't need to have separations. We probably don't need to have it anyway, but we certainly wouldn't need it if all we did was enforce border law. I sug-

gest maybe we just do one of the simple things and maybe just agree with the President that the border ought to be enforced. We shouldn't have an open border.

I yield back.

Ms. DELAURO. Congresswoman Lee.

Ms. LEE. Let me ask a question just to clarify who has the authority—well, in terms of the MOA and its rescission, who has the authority to sign for the rescission and who signed it initially?

Mr. HAYES. I do know that the former Director of ORR signed it, as well as the acting director—I am sorry, the Acting Assistant Secretary of Children and Families. I am honestly not sure at DHS who signed it, ma'am. I have read it, but I can't remember specifically, so I would not want—

Ms. LEE. And who can rescind it? Who has the authority to rescind it?

Mr. HAYES. I would assume the agencies that all signed it. Definitely above my pay grade, but—

Ms. LEE. Well, okay, would it be the Secretary of HHS, maybe?

Mr. HAYES. No. It was at the Assistant Secretary level. I can, without a doubt, say that the former director of ORR and the former Acting Assistant Secretary of Children and Families inside HHS were two of the signatories. I cannot remember who signed it from DHS.

Ms. LEE. Does anyone know? Ms. Maxwell, does anyone know who has the authority to rescind this?

Ms. MAXWELL. No, I do not know that.

Ms. LEE. Can you get back to us in writing who has the authority to rescind the MOA?

Mr. HAYES. I will be happy to work with our Assistant Secretary of Financial Resources and a team at HHS and get that answer back.

Ms. LEE. Okay, thank you. Let me ask you another question with regard to the children and the treatment. First of all, policies that have been created by this administration have very serious future potential problems if not dealt with properly as it relates to the appropriate type of mental health services.

I want to read to you, again, the National—this is from the National Child Traumatic Stress Network, which gives us a glimpse of what could happen if, in fact, these children aren't treated properly.

They said: "Complexly traumatized children are more likely to engage in high-risk behaviors, such as self-harm, unsafe sexual practices, and excessive risk-taking, such as operating a vehicle at high speeds. They may also engage in illegal activity, such as alcohol and substance abuse, assaulting others, stealing, running away and/or prostitution, thereby making it more likely that they will enter the juvenile justice system."

Now, this characterization really does outline the high stakes associated with proactively mitigating the impacts of childhood trauma. So I think—and I am wondering, Commander White, have you all thought this through all the way out? Because I foresee some very difficult issues that these children are going to face as a result of the trauma that they have experienced, and not treating them

properly, just in terms of some of these issues, but also in terms of other public safety, national security issues.

I mean, how do you think someone is going to feel at 18 years old that they were taken from their parents, and then they were treated in a way that wasn't healthy, and that did not help restore their mental health as a result of PTSD?

Mr. WHITE. So, Congresswoman, all of the outcomes that you describe are well-supported by the evidence and the science for children who have sustained prolonged and complex traumatic experiences. This has long been part of the planning within ORR for the care of unaccompanied children.

As I said before, separated children pose a unique problem, one that I think the program is not designed to respond to. But the one caveat that I would say in the list of outcomes you have said is that the best evidence that we have would suggest that the children in our program are at lower risk of committing serious crimes than children in the domestic child welfare environment. And given that sometimes they have been characterized publicly as a high crime risk, I want to clarify that record.

Ms. LEE. And I am not saying they are now. I am talking about long term, if you don't treat traumatized children with the appropriate psychotherapy long long-term care.

Mr. WHITE. We agree, ma'am. And this is part of the long-standing and evolving process of planning for the mental health needs of the very specific population of unaccompanied children who enter the country without parents, often fleeing poverty and violence, which is the population we serve. Yes, ma'am.

Ms. LEE. With children separated from their parents, you have that added element of anger.

Mr. WHITE. Yes, ma'am.

Ms. LEE. So how do you address anger management and how do they work through that anger in the type of treatment that you are proposing?

Mr. WHITE. So fundamentally, as I said before, I do not believe the UAC program is designed or capable of meeting the behavioral health needs of separated children. The only way to prevent that harm is to prevent separation.

Ms. LEE. Yeah, but you have got children now you have got to address.

Mr. WHITE. Correct.

Ms. LEE. So we have got to figure this out. And I believe that some outside mental health organizations, such as the American Psychiatric Association, such as the National Child Trauma Stress Network, such as the pediatricians. I think you need some help with this.

Mr. WHITE. Many of those partnerships are underway. I just want to speak to the reality that separation cannot be managed with a tertiary intervention strategy, only by preventing separation.

Ms. LEE. I understand that. I started my comment earlier by African Americans, the policy of separation of children 400 years ago, the generational impact.

Mr. WHITE. Yes, ma'am. The historical verdict on family separation is in.

Ms. LEE. It is in. And so, hopefully, you will have learned from this and, hopefully—I don't want to hear saying, We can't do anything, or that this is a population of children that we just don't have an approach or a solution to, because if not, you are going to have thousands of children with this long-term trauma that is going to be transmitted to their children through DNA changes.

Mr. WHITE. Yes, ma'am. If that is how I came across, that was not my intention. The reality is most of the separated children were discharged under an expedited court ordered reunification process. But the fundamental reality is while we continue to work on best efforts to respond to their needs, we cannot plan for future separations. Instead, it is the job of everyone, including Congress, to prevent them.

Ms. DELAURO. Congresswoman Clark.

Ms. CLARK. Thank you, Madam Chairwoman.

First, I just want to share our witnesses that our Congress ladies do understand the complex social and economic factors in the Northern Triangle that impact immigration into this country, and we also understand that threats to withdraw aid from those countries do not help, that policies like remain in Mexico do not help, and make your jobs, trying to meet the needs of these children and families and deal with the trauma they have suffered and their long-term mental health, even more difficult.

Director Hayes, back when you were here on July 1st, we talked about providing this subcommittee with additional information on sexual assaults. I wondered if you could give me an updated timeline for the release of the prevention of sexual abuse reports, and if you have any preview for the subcommittee on some of those findings, on how they may impact change in ORR policies.

Mr. HAYES. So I believe those reports have been posted. If they have not, they will in the very near future. And I will definitely go back and check with the team and work through the Assistant Secretary for Financial Resources and her team to communicate that back to you.

What was the second question, ma'am?

Ms. CLARK. If you could give us a preview of any of those reports and any proposed change in policies you might be proposing in response.

Mr. HAYES. Well, I would just say that, you know, we have late—end of last year, we did hire the Prevention of Sexual Abuse Coordinator, and that is a team that we are building and seek to further build at ORR. And we will continue to remain engaged according with applicable laws and ORR policies and procedures. Yes, ma'am.

Ms. CLARK. Ms. Maxwell, the OIG also recently released a report on ORR's facilities' adherence to background checks. I wonder if you could tell me are there any gaps that facilities faced in conducting those appropriate background checks?

Ms. MAXWELL. Thank you. That is correct. We did release that report in conjunction with this report and found that, generally speaking, facilities were adhering to the required background check screenings necessary to protect children.

We did find some gaps, though, as you mentioned, and in particular, one of the areas we found over half the facilities were al-

lowing clinicians to work with children prior to the results of the background check being submitted to the facility. We did alert ORR immediately about that fact, and ORR has taken action, putting out information and reminding facilities that clinicians should not be allowed to work with children until the background check results are in.

We also had some concerns about waivers for the CAM checks, and, again, that issue has been addressed by ORR. So we have other recommendations out there, but we continue to work with the administration to make sure that all the background checks are in place.

Ms. CLARK. Great.

Do you have anything to add, Director Hayes, into how you are addressing these issues in background checks?

Mr. HAYES. No. I just would add, Chairwoman DeLauro, Congresswoman Clark, I think it was on the tour that you all both were on, but in regards to some potential changes to TVPRA and has, one of your colleagues also talked about aunts and uncles maybe being in that category as well. So when you all have that discussion, I would just encourage you to consider that as well as maybe being potentially close family in a lot of these situations in families.

Ms. CLARK. Thank you. I yield back.

Ms. DELAURO. Thank you.

Let me now yield to the ranking member, Congressman Cole, for any further comments or questions.

Mr. COLE. Thank you very much. I will try and be brief, Madam Chair, but I want to end where I began. I want to thank you for the hearing, and your focus on this issue. And we have a lot of pretty serious debates about immigration, what is appropriate and what is not appropriate, but I think we all agree that any child that comes into the custody of the government of the United States needs to be taken care of and well-treated. And I think we have come short in some cases, but I think you have pushed us in the right direction, and you ought to be proud of that. I am proud of you for doing it.

Second, again, I want to thank you, Madam Inspector General Maxwell. I know you are an assistant, but we are going to elevate you today, because I just think you have done a great job here. I think this is a great service, and it is exactly what we ask inspectors generals to do, to go and provide us with the information we need to make appropriate decisions.

I want to thank you too, Director Hayes, again, and Commander. I had the opportunity to visit the border with you. I think things have gotten measurably better during your tenure. I don't have any doubt about your dedication to try and take the information that Ms. Maxwell has given you and respond appropriately, within the limits of your resources. And, fortunately, Congress expanded those resources in July, something we need to think about going forward.

We were overtaken by this crisis in 2014. You know, we are re-living this, and I am not sure that we prepared very well in between for this happening to us again. And, again, I don't have any magic solutions for what is going on in the Northern Triangle countries, but I suspect this won't be the last surge that we see.

So being a little bit better prepared and recognizing this may come again, and institutionalizing some of these things I think is important as we go forward. I know you are dealing with the challenge you have now, but at a future time, I would welcome your thoughts—and I know you guys are thinking about this—as to what we need to do to make sure that if we have a situation like this, we are a little bit better prepared to deal with it than I think we were this particular time.

So, with that, again, I think this is a little case study in how Congress ought to work. It is real oversight. It is good information from the executive branch to act on. It is a response by the executive branch, and a listing of what you need, and its expiration, this whole discussion about what we need to do going forward. I think that is a valuable exercise.

Again, I don't have the answers to all that, but I think this moved us in the right direction in this hearing, and certainly the manner in which each of you have discharged your responsibilities to the country, quite frankly. And I thank all three of you for doing that.

Madam Chair, good hearing. I think we made good progress.

Mr. HAYES. Thank you for the kind words, sir.

Ms. DELAURO. Thank you very, very much, Congressman Cole.

Let me just do a couple of housekeeping things, if I might. This is with regard to two letters to HHS. It was a letter sent by the ACLU regarding the influx facilities. That was flagged for the administration, so we can get you further information on that. Also, if you could respond to a letter that was sent by public health officials regarding the flu vaccinations. The vice chair and I flagged this letter for HHS as well. So we are awaiting the response on those letters, so if we could get that, that would be terrific.

Mr. HAYES. Madam Chair, do you have some dates on those, by chance?

Ms. DELAURO. We will get those to you, no question. And we will be wanting just to submit some questions for the record. You do not have to address these. It is because TVPRA has mandated post-release services, that I understand that there are hundreds of children who qualify, and they are on a wait list. If we can just know how long the children are waiting before they are connected with post-release service, and have the wait times increased. Again, we will get you the questions. You don't have to—and what are the efforts that ORR is taking to expand the post-release services capacity, and the use of the \$2.9 billion in the supplemental and how we go forward for 2020.

And I will get a couple of other questions, which I know that have to do essentially with post-release services.

Let me just comment on a service that Congresswoman Roybal-Allard mentioned to me, that there is something of a traveling nurse program, where there is a pool of nurses who you can apparently tap into and that are available. They get back in less than a day, et cetera, et cetera. And we can find out more about that and link that up with you, in terms of services, because I continue to be interested in the kinds of direct services that you are able to provide. And just as a point, it is less than \$600 a day for nurses.

So let me come to a conclusion here today. I really so sincerely thank you for the time and the thoughtfulness of your testimony and the thoughtfulness of the work that you do every day. I think one of the things that we have established is that the administration's policies, in fact, have traumatized thousands of children. I am not going to dwell on that. I dwell on it a lot, but I think we do need to move forward. But I think we have established that some of these policies have put children at grave risk. And so the fact is, is that how do we try to deal with it?

And, Commander, you spoke about prevention, just as you talked about, and how do we prevent this from happening? You also did something very special, I think, Commander. So often, we all hear that these children are programmed to tell us a story about what happened to them, and they are just given a line, and whether it is a coyote or someone else who got them here, or how they got here, you know, and that they are parroting something that someone told them to say in order to gain access to the United States.

One of the things that you talked about were the horrific circumstances that some of these children have faced. Congresswoman Roybal-Allard pointed out the directives that some were given. So it is not made up. There is a reality here, which I believe we have to face, and have to address, and deal with, in a humanitarian way, and, again, that we added to that trauma for these children. We have to take responsibility for that.

And I, too, some would say, you know, my colleagues will tell you on both sides of the aisle, I suppose I am an equal opportunity antagonist to whomever is in the White House, because we have to do what is right. Improvements have been made, and take credit for the directives, but, as we know from the testimony, that there are current policies that we need to address.

And specifically, I know I am a broken record, but the memorandum of agreement has got to go. Let's find out who has that authority. I know what the Assistant Secretary said; she would rescind it. Let's do that. Let's do it and make the changes. Accountability is where we need to go, and we talked about that. And Chairman Cole spoke about that as well as where do we go subsequently here to follow up, to make sure of what is happening here.

We have to carry out the recommendations. Concurrence with the recommendations is not enough, and I say that to you, both of you. I say that to the IG. And you are following up, and that is our responsibility as well. It is not here today, gone tomorrow. We cannot forget about it. We cannot forget about it. You have tough jobs, very difficult jobs, but you have a lot of good people who want to do the right thing. And we need to work together. And I will commit to you, as we have in the past, that with regard to services, if they are going to be carried out, we will have to provide the resources for that, because this was wrong.

I also would talk about the discharge. I am singularly focused on the discharge, and I believe we can do it. We have been able to do it. We have demonstrated that we can do it. So that we do not need influx facilities, which are not State-licensed, but that we have a way that will help to try to make sure that we have State-licensed facilities that can deal with the issue rather than case managers, people taking care of kids who are not checked out, have not been

vetted the way they should. Let's follow both the letter and the spirit of the law, where we want to try to address these issues.

You know, and it is the State of Texas, I will just say, defines child abuse as inflicting or failing to responsibly prevent others from inflicting mental or emotional injury, impairing a child's growth, development, or psychological functioning. And I am not saying this to you, because you are trying to take us down a good road, but people have to be accountable. Those who employed a policy that would take us in this direction have to be brought to task in some way. Let's not follow a path of child abuse. No one here wants to do that. That is not what you came to do, in terms of your public service. It is not who you are.

So let's use the power of the agency to make the decisions about what happens to those children who are in our care, and let's make sure we take good care of them while they are here and make sure they have good care when they are discharged, and to discharge them as quickly as we possibly can, and as safely as we possibly can.

I want to, again, say thank you for your time, for your commitment. And that concludes today's hearing. Thank you.

[Answers to submitted questions follow:]

Committee on Appropriations
Labor, Health & Human Services, and Education Subcommittee
Oversight Hearing: Mental Health Needs of Children in HHS Custody (9.18.19)

Questions for the Record

Submitted by Congressman Cole

Unaccompanied Alien Children

Question: What direct medical or mental health service is paid for by HHS after a child is placed with a sponsor? Does HHS have the authority to provide for these services after placing a child with a sponsor? What authority does HHS have to provide for services after placement with a sponsor? What services does HHS currently provide for a child after placed with a sponsor?

RESPONSE: HHS does not pay for any direct medical or mental health services after a child is placed with a sponsor. HHS does not have authority to provide direct services after a child is released from ORR care.

HHS is required to offer post-release services (PRS) when ORR conducts a home study for a prospective sponsor, and is authorized to provide PRS for certain children who could benefit from ongoing assistance from a social welfare agency upon release (e.g., for children with ongoing mental health needs). See 8 U.S.C. 1232(c)(3)(B). PRS providers coordinate referrals to supportive services in the community where the children reside, and provide case management services. PRS are not direct health services (for example, ORR does not provide mental health counselors for children after release), nor are PRS intended to serve as child welfare checks on released children.¹ Further, PRS are voluntary. The sponsor must consent before services are provided, and may withdraw consent any time after services start. See ORR Policy Guide 2.7.2 Approve Release with Post-Release Services, available at <https://www.acf.hhs.gov/orr/resource/children-entering-the-united-states-unaccompanied-section-2#2.7.2>.

ORR refers a child for PRS when:

- The child received a home study;
- The child is released to a non-relative sponsor;
- The release was determined to be safe and appropriate, but the unaccompanied alien child and sponsor would benefit from ongoing assistance from a community-based service provider. For example, ORR refers children with ongoing health concerns related to Zika virus for PRS (see ORR Policy Guide 2.8.5 Post-Release Services for UAC with Zika

¹ Because PRS case workers are mandatory reporters, they would report any suspected case of abuse or neglect in accordance with state law.

Virus Disease or Infection, available at <https://www.acf.hhs.gov/orr/resource/children-entering-the-united-states-unaccompanied-section-2#2.8.5>).

See generally, ORR Policy Guide 6.2 Post Release Services, available at <https://www.acf.hhs.gov/orr/resource/children-entering-the-united-states-unaccompanied-section-6#6.2>.

PRS providers must be culturally and linguistically appropriate when connecting the child and sponsor to resources within their local community. The PRS provider coordinates services that promote access to services in the areas of: placement and stability; immigration proceedings; guardianship; legal services; education; medical services; individual mental health services; family stabilization and counseling; substance abuse; and gang prevention, as needed and appropriate for the specific child and/or sponsor.

For children referred for a trafficking concern, or who meet the specific criteria for a home study under the TVPRA, PRS continue during the pendency of their removal proceedings. PRS must end when the child turns 18 or when the child's immigration case is terminated by an immigration court. For all other children referred for PRS, PRS must end either after 90 days or when the child turns 18, whichever happens first. PRS may also be terminated where a child welfare professional determines that they are no longer needed.

Committee on Appropriations
Labor, Health & Human Services, and Education Subcommittee
Oversight Hearing: Mental Health Needs of Children in HHS
Custody (9.18.19)

Questions for the Record

Submitted by Chair DeLauro

Post-Release Services (PRS)

The table in the ACF's response to Recommendation 1 in the report suggests that 40% of children released from ORR's care in FY2018 were released with PRS even though the number of UAC served by PRS each year includes "ongoing" cases, which makes the 40% figure misleading.

Question: How many children were released *without* post-release services for FY18 and FY19 to date?

Response: We would note that calculating those children who receive post-release services in a given fiscal year (FY) may be complicated by factors such as delays in assigning a post-release service case worker between fiscal years. For example, there are cases where a child released in September of a given year is referred for post-release services (PRS), but not actually assigned a case worker until October. Waitlist times and children who are identified as needing PRS *after* release from ORR custody (as opposed to children referred for services prior to release while in ORR care) are other complicating factors

Keeping these factors in mind, in FY 2018 approximately **27,000** UAC were discharged *without* PRS (out of 40,762 UAC discharged), and in FY 2019, as of October 21, 2019, there were approximately **54,000** UAC who were discharged *without* PRS (out of a total of 77,731 UAC discharged).

Question: Would a child with mental health needs automatically be referred for post-release services by the case manager or clinician?

Response: Referrals for PRS depend on the level of the child's specific needs and the availability of community-based mental health services to meet that child's needs. These services are not mandatory, and the UAC and their sponsors may choose to opt out of receiving the services.

The Trafficking Victims Protection Reauthorization Act (TVPRA) requires referral for PRS whenever a child has a home study, regardless of the basis for the home study. See 8 U.S.C. 1232(c)(3)(B). Additionally, ORR has the discretion to provide PRS for children with mental health or other needs who could benefit from ongoing assistance from a social welfare agency.

When a UAC is referred to ORR, the child receives a comprehensive medical examination and mental health screening during the admission process. If a UAC is determined to have serious mental health needs, the clinician will refer the minor to appropriate mental health service providers while in care, as necessary, if such services cannot be adequately addressed by clinical staff at the child's placement. Throughout the release process, care providers work with the child and sponsor to prepare an after-care plan. Through its network of PRS providers, ORR facilitates access to community resources and services for children and sponsors who would benefit from ongoing assistance. ORR PRS providers themselves provide only case management services.

Question: What criteria and training do case managers and staff have to identify mental health needs and then refer a child for post-release service?

All care providers have a licensed clinician on staff whose responsibilities include assessing the mental health needs of children in care. Clinicians have master's degrees in social work, psychology, or other relevant behavioral sciences and are trained on common health and mental health issues specific to children as well as child development theory and working with children who are victims of abuse and neglect. These trainings are required as part of a care provider's cooperative agreement with ORR. Further, licensed clinicians assess the mental health needs of children in care and work closely with case managers to make appropriate referrals for post-release services.

ORR's Division of Health for Unaccompanied Children (DHUC) recently created a six-part Mental Health Literacy Training Series, intended to introduce audiences to basic concepts in mental health and equip all individuals within the UAC program with the appropriate tools to communicate clearly, effectively, and accurately about mental health concerns. The series consists of the following modules: basic psychopathology, basic psychopharmacology, suicidality and non-suicidal self-injury, sexuality and gender identity, education issues, and behavior modification. The entire training series spans 12 weeks, with a new module being presented every two weeks. Each module is presented three to four times over the two-week period in order to accommodate programs across different time zones, and to provide alternative sessions for those with scheduling conflicts.

Post-Release Services Backlog

It's my understanding that hundreds of children qualifying for TVPRA-mandated post-release services are on a waitlist. Thousands of other children flagged to receive services are waiting weeks or even months before they receive these critical services.

Question: How long are children waiting before being connected with a post-release service provider and how have these wait times grown in recent months?

Response: Between February 6, 2018, and October 16, 2019, the average wait time for PRS was 103 days. ORR has received a record number of UAC referrals in FY 2019, which has led to an increase in the average wait time for PRS services as more children needing PRS services are identified and added to the waitlist. As of November 12, 2019, ORR has had a waitlist of 800 children waiting for an assigned post-release service case worker at any one time.

Question: What efforts is ORR taking to expand its post-release services capacity and how is ORR using the additional funding provided in the FY19 Supplemental for post-release services in order to provide for the mental health needs of children after they leave ORR's care?

Response: In response to the unprecedented number of referrals in FY 2019 (which led to a corresponding increase in the number of PRS eligible children), ORR issued a solicitation to current home study and PRS grantees to submit proposals for supplemental grants for the remainder of the grant project cycle that ends in January 2020. The current grant project will be extended through June, and the new grant project cycle will run from July 2020 through June 2023. As previously mentioned, PRS grantees do not offer direct services but identify and refer minors and their sponsors to service providers after their release from ORR care. The money allocated will be for case management services, and not specifically for mental health services.

Question: Do you anticipate being able to entirely clear the post-release services waitlist with the funding appropriated in the FY 19 supplemental and what can be done for FY 20 to ensure that such a waitlist does not build back up?

Response: ORR is currently processing a grant award, which will allow ORR to expand its PRS capacity such that it can clear the backlog or at least significantly clear the waitlist. In addition, ORR will continue to monitor the number of referrals to ORR and demand for PRS. The funds from the supplemental will also be used if there is an increase in the number of UAC that qualify to receive PRS.

Mental Health Clinicians

It's my understanding that hundreds of children qualifying for TVPRA-mandated post-release services are on a waitlist. Thousands of other children flagged to receive services are waiting weeks or even months before they receive these critical services.

Question: Do mental health clinicians working in ORR facilities have access to training opportunities in evidence-based child trauma treatments and interventions?

Response: Yes, as previously mentioned, ORR DHUC has developed a six-part Mental Health Literacy (MHL) Training Series. The first module, basic psychopathology, focuses on both trauma backgrounds and micro-traumas often present in many UAC histories and accumulated along their travels. Also, in collaboration with the National Child Traumatic Stress Network (NCTSN), a four-part webinar series entitled, "Trauma-Informed Care: Understanding and Addressing the Needs of Unaccompanied Children," was developed. The four-part webinar series is currently being piloted

at Cayuga Centers, and ORR is working on a roll-out plan to distribute the webinar series across its network of shelters.

Question: Given that mental health clinicians in ORR facilities are regularly exposed to difficult trauma content and narratives, how is ORR training and supporting its personnel who may be experiencing secondary traumatic stress?

Response: The MHL Training Series discusses secondary trauma in the context of post-traumatic stress disorder. The MHL Training Series also stresses to care providers the importance of caring for oneself in order to provide the best care possible to the child. Similarly, the fourth module of the NCTSN/ORR webinar series, “Secondary Traumatic Stress: Understanding the Impact of Trauma Work on Professionals,” addresses secondary traumatic stress.

In ACF’s response to Recommendation 2, it says “ORR has made additional funding for continuing education available to licensed clinicians as a retention strategy.”

Question: How much funding is being spent on this strategy and how is it being distributed to grantees and/or clinicians?

Response: ORR grantees allocate funding towards Continued Education Units. This is a line item in their budget, and it is an allowable expense under their cooperative agreement. On average, each ORR grantee budgets between \$100 and \$150 for each clinician’s training and/or certification.

Younger Children in ORR’s Care – Grantee Guidance and Modifications

Question: Did HHS or ORR issue guidance or provide support to grantees as they reported challenges associated with caring for children that were so much younger, and presented such different needs from the teenagers they typically served?

Response: ORR is deeply committed to providing for the physical and emotional wellbeing of all children in its temporary care. Care providers must deliver services in a manner that is sensitive to the age, culture, native language, and needs of each UAC. Further, across the national UAC program, ORR ensures that care provider staff are trained in techniques for child-friendly and trauma informed care. ORR’s Project Officers (PO) and Federal Field Specialists (FFS) assigned to the programs promptly address any challenges related to caring for young children, if experienced. Additionally, care providers are licensed to provide care to children in certain age ranges (some providers serve only older teenagers, others provide care for small children) or special populations (pregnant/parenting teens; teenagers undergoing sex offender treatment, etc.). Further, ORR staff conduct onsite visits as well as desk monitoring on a weekly basis. Through these monitoring activities, ORR identifies instances where care providers are out of compliance with ORR’s policies. When a program fails to meet the standards set forth by state licensing or ORR’s policies and procedures, POs and FFSs issue corrective actions and provide technical assistance to help care providers address any challenges or areas of non-compliance as reported in ORR’s findings.

Question: Does ORR have and enforce a protocol or set of procedures for providing care to children under age 3?

Response: ORR ensures that all the children in its custody, including children who are under age three, are cared for in the least restrictive, safe, and nurturing environment. Per ORR policy, ORR typically places very young children who do not have immediately available sponsors in ORR-funded foster care placements, because such family-based placements better meet the particular needs of very young children. Like all State-licensed facilities, ORR foster care programs must meet both ORR and State-specific requirements, including State licensing requirements and child welfare requirements, and are subject to monitoring by both ORR and State authorities. ORR ensures that programs meet its standards through regular monitoring and monthly on-site visits.

Question: Did ORR increase family foster placements to accommodate the younger population of children that were being referred from CBP? How many children were placed in single family homes versus how many were placed in group settings?

Response: ORR strives to attain optimal shelter and foster bed care capacity to ensure ORR can promptly place children referred to our care at any given time. ORR recently funded 20 grants for transitional foster care and shelter care beds under a Funding Opportunity Announcement (FOA) published on March 25, 2019. As a result, ORR increased its overall funded bed capacity to over 15,000 beds. In addition, ORR issued a new FOA for transitional foster and shelter care beds in September 2019 to replace expiring grants, and potentially further increase permanent bed capacity, if needed.

ORR prioritizes placing tender age children in transitional foster care programs over other levels of care whenever possible. The majority of foster care placements are in single-family homes or smaller group homes/shelters. Below is a breakdown of the number of tender age children who were in ORR custody on October 23, 2019.

Tender Age (0-12) UC By Shelter Type	Number of UAC In-Care	% of UC In-Care
Standard Shelter	257	34.6%
Transitional Foster Care	447	60.2%
Residential Treatment	2	0.3%
Therapeutic Group Home	1	0.1%
Long Term Foster Care	36	4.8%

Committee on Appropriations
Labor, Health & Human Services, and Education Subcommittee
Oversight Hearing: Mental Health Needs of Children in HHS
Custody (9.18.19)

Questions for the Record for the Department of Health and Human Services

Submitted by Congressman Pocan

Vacant Influx Facilities

During the Appropriations Committee entitled Mental Health Needs of Children in HHS Custody that the Office of Refugee Resettlement (ORR) is currently spending “about \$600” per day, per bed, at the vacant Homestead Temporary Emergency Influx facility. I am interested in the answers to the questions below around other facilities under contract with ORR.

Question: Which facilities have vacant beds as of the date of the hearing, September 18, 2019? For each facility, please indicate if it is owned and operated by the federal government, a non-profit organization, or for-profit entity.

RESPONSE: Please see the attached PDF titled, “Bed Vacancy 9.18.19 by Program” for this information. All facilities, except for the ones highlighted in light blue or light orange, are operated by non-profit organizations on property that they own or lease. The facility highlighted in light blue is on federal land leased by ORR and operated through a contract awarded to a for-profit entity. The facilities highlighted in light orange are operated by for-profit entities on property that they own or lease.

Question: How many vacant beds exist at each facility listed in response to the above question?

RESPONSE: Please see the attached PDF titled, “Bed Vacancy 9.18.19 by Program for this information.

Question: What is the cost to maintain one vacant bed at each of the facilities named in response to the preceding questions?

RESPONSE: Currently, the average cost per day for a bed at a permanent shelter is \$262.00. Eighty percent of the daily cost rate is due to staffing costs for the estimated amount of children each program can serve. The other 20 percent of the daily cost is for supplies for each child. When there is no child and a bed is vacant, there is approximately a 10 percent reduction in the daily cost of the bed.

The cost to maintain an individual bed is subject to change depending on overall bed capacity. ORR is continuing to develop efficient, cost-effective strategies to address historical variations in the number of children apprehended at the border. Temporary influx care facilities carry higher costs associated with quick facility standup and the need to hire staff quickly and on a temporary basis, but other costs can be significantly reduced or eliminated when capacity is not needed.

Question: How long will you continue to operate vacant facilities?

RESPONSE: ORR has no vacant operational facilities.

ORR uses a series of data points and trends to determine its bed capacity needs. This includes levels of placements, referrals, and discharges over previous months and years. However, ORR's short-term and long-term capacity needs are always subject to change, as there is no definitive method to gauge the amount of future unaccompanied alien children (UAC) that will come into ORR care

Other ORR Emergency Influx Facilities

Question: How many active temporary influx shelters does ORR have current contracts with?

RESPONSE: There are no children at any ORR influx facility. ORR currently has both influx facilities on warm status. Should ORR have a need for an influx facility, warm status allows the agency to re-open the facility in short order.

Question: Are there any unaccompanied children at the Carrizo Springs facility as of this date? Are there any unaccompanied children at the Fort Sill facility as of this date? Are there any unaccompanied children at any other facility that ORR contracts with? If so, please provide a list of their ages, where they are being housed, how long they have been at the facility where they are housed and how long they have been in ORR custody.

RESPONSE: As of July 25, 2019, there are no UAC housed at Carrizo Springs Influx Care Facility. As of August 3, 2019, there are no UAC housed at Homestead Influx Care Facility. ORR has not placed any children at Fort Sill since 2014. The Homestead Influx Care Facility is the only ORR shelter providing care for UAC through a contract. All other UAC currently placed in ORR are in facilities funded through grants operated under the terms of a cooperative agreement.

Question: If Fort Sill and Carrizo Springs are empty, what are the costs per-bed, per-day to keep the facility active? How long does ORR plan to keep them open while they are vacant?

RESPONSE: Fort Sill does not have any costs. Given the declining in-care census and the requirement by Department of Defense that it return to Fort Sill by the end of September, ORR deactivated the site before receiving any children. On August 28, 2019, ORR notified the

appropriate congressional offices, state and local elected officials, and other stakeholders that it deactivated the Fort Sill site as a temporary influx shelter.

The estimated costs to keep Carrizo Springs in warm status are approximately \$95 per bed per day. The final costs will be reconciled once the supplemental grant ends. The majority of the funds are used for improving site infrastructure, which will ultimately save the government on infrastructure mitigation costs when the lease term ends.

Permanent ORR Facilities

Earlier this year, Congress passed the Emergency Supplemental Appropriations for Humanitarian Assistance and Security at the Southern Border Act, which made \$866 million available to expand the supply of shelters for which State licensure should be sought. Your agency also made an announcement in July 2019 that it would double its capacity for permanent shelters to 20,000 beds, while keeping 3,000 beds available at unlicensed facilities.

Question: Has ORR created any new permanent shelters since the Supplemental Appropriations Act was enacted in July? If so, please provide a list of where those shelters are located; whether ORR has received state licensure for these facilities; whether ORR is in the process of obtaining state licensure for these facilities; the bed capacity at each facility; and the contractor ORR is using at those locations to provide services.

RESPONSE: Please see the attached PDF titled, “Permanent ORR Facilities,” for this information.

Please note that ORR does not obtain or participate in the process of obtaining state licenses for new permanent shelter beds. Rather, grantees are responsible for obtaining and maintaining state licensing for permanent shelter beds obtained under the ORR residential Funding Opportunity Announcement process. This process usually takes several months to a year.

Question: What is the rationale for keeping 3,000 beds available at unlicensed influx shelters? At what influx shelters are those 3,000 beds located? What is the per-bed, per-day cost for these 3,000 beds when they do not have unaccompanied children at the facility?

RESPONSE: ORR projected needing up to 3,000 beds at temporary influx facilities. This projected number comes from the potential baseline bed capacities ORR could bring online quickly at Carrizo Springs (approximately 1400) and Homestead (approximately 1200-1500).

Currently, the Homestead Influx Care Facility is on “warm status” (when an influx care facility is on “warm status” ORR does not place any children at the facility but the site is maintained with the minimum number of support staff to keep the facility safe and secure) which allows the agency to activate the facility, as needed. ORR is still developing a refined cost estimate based

on the current activity level. As of late October, staff are beginning to demobilize. Since the contracts for operating the Homestead Influx Care Facility are cost reimbursement contracts, the ceiling/maximum costs approved would not change significantly between active and warm status without children placed there. For Carrizo Springs, the estimated cost per bed, per day is \$95 while the facility is in warm status.

The cost to maintain an individual bed is subject to change depending on overall bed capacity. ORR is continuing to develop efficient, cost-effective strategies to address the historical variations in the number of children apprehended at the border. Temporary influx care facilities carry higher costs associated with quick facility standup and the need to hire staff quickly and on a temporary basis, but other costs can be significantly reduced or eliminated when capacity is not needed.

ORR uses a series of data points and trends to determine its capacity needs, including the need for temporary influx facility beds for events not related to a surge of UAC at the border (e.g., a natural disaster or other emergency event that would disable a permanent shelter's ability to care for children or operate). The data points and trends ORR considers includes levels of placements, referrals, and discharges over previous months and years. However, ORR's short-term capacity needs are always subject to change, as there is no definitive method to predict the numbers of UAC that will come into ORR care in the future.

WEDNESDAY, SEPTEMBER 25, 2019.

INVESTMENTS IN MEDICAL RESEARCH AT FIVE INSTITUTES AND CENTERS OF THE NATIONAL INSTITUTES OF HEALTH

WITNESSES

FRANCIS COLLINS, M.D., PH.D., DIRECTOR, NATIONAL INSTITUTES OF HEALTH

BRUCE TROMBERG, PH.D., DIRECTOR, NATIONAL INSTITUTES OF BIOMEDICAL IMAGING AND BIOENGINEERING

HELENE LANGEVIN, M.D., DIRECTOR, NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH

PATRICIA FLATLEY BRENNAN, R.N., PH.D., DIRECTOR, NATIONAL LIBRARY OF MEDICINE

ELISEO PÉREZ-STABLE, M.D., DIRECTOR, NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

CHRISTOPHER AUSTIN, M.D., DIRECTOR, NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

Ms. DELAURO. The subcommittee will come to order. Thank you all very, very much, and again, we apologize for being late. The days take on a life of their own.

So, but I wanted to say good morning. Good morning, Dr. Collins. Welcome back to Labor, HHS, to the Appropriations Subcommittee. Let me just say a thank you on behalf of the subcommittee for hosting members of the subcommittee for the site visit at the NIH campus last week.

We had a real wonderful opportunity to learn more about NIH's work. We met with the researchers who were working to cure sickle cell disease, to develop treatments for major depression, shrink and treat cancer tumors in children. We heard from participants whose lives have been changed by clinical trials. So it was a moving—an informative, but a very moving experience as well.

Let me welcome our witnesses, including the five Institute and Center Directors who join us today. And in addition, and always a great addition, Dr. Francis Collins, who has joined us many times, Director of the National Institutes of Health; today joined by Dr. Bruce Tromberg, Director of the National Institute of Biomedical Imaging and Bioengineering; Dr. Helene Langevin, Director of the National Center for Complementary and Integrative Health; Dr. Eliseo Pérez-Stable, Director of the National Institute on Minority Health and Disparities; Dr. Patricia Flatley Brennan, R.N. and Ph.D., Director, National Library of Medicine; and Dr. Christopher Austin, Director of the National Center for Advancing Translational Sciences.

Your work, all of the 27 Institutes and Centers, leads to treatments and cures for diseases and conditions that affect people

around the globe. It is transformative and some of the greatest good that we can do in Government.

And each year, this subcommittee holds a budget hearing to hear from the NIH Director, as well as Directors of five or six of the Institutes or the Centers. But today's hearing is an opportunity for the subcommittee members to hear more and to hear from Directors of an additional five Institutes and Centers, which was very, very important to all of us.

When I joined the subcommittee about 25 years ago, we used to invite every Director to testify. It has been a long time since we have heard from many of them. So, in fact, I am going to be plain-spoken about this, and my ranking member, Congressman Cole, knows about this. I wanted to include the National Institute of Nursing, I wanted to include the Fogarty International Center, and the National Eye Institute as well this morning. Unfortunately, the administration denied our request on the grounds that we did not provide 2-week notice.

I am disappointed, but nevertheless, we will find another opportunity to hear from other Directors.

Again, I think we ought to be inviting every Director at least every 2 or 3 years to be able to listen to what you are doing and how we can assist in that process. It is critical for the subcommittee to get a picture, a full picture of the NIH's portfolio as well as the research landscape.

So you have heard me say before, with each scientific discovery, each medical breakthrough, the NIH advances human knowledge. It improves our quality of life, and above all, it saves lives. I am so proud that the Congress increased the NIH funding by \$9,000,000,000, or 30 percent, over the past 4 years.

And I will note that the subcommittee did this on a bipartisan basis. So, in fact, for 2020, the House-passed appropriations included increased funding consistent with significant annual increases over the last 4 years. The House bill increases funding for each of the Institutes by at least 5 percent.

Our funding bill is a statement of our values and a reflection of our commitment to investing in basic biomedical research at the NIH. It is not overstating the case to say that the NIH has prolonged or improved the life of every American. Because of NIH research, we have decreased childhood cancer mortality 50 percent in 35 years. We have a vaccine to prevent cervical cancer. We have a drug that prevents HIV transmission with 99 percent effectiveness.

In fact, a recent study in the Proceedings of the National Academy of Sciences in February found that NIH-funded research contributed directly or indirectly to every single one of the 210 drugs approved by the FDA between 2010 and 2016. That is your impact, and it is amazing.

So to our guests, we say thank you for everything that you do. We look forward to our conversation today.

And now let me turn this over to my colleague from Oklahoma, the ranking member of this subcommittee, Mr. Cole, for any remarks.

Mr. COLE. Thank you very much, Madam Chairman.

I have a couple housekeeping things first, if I may? I want to just say it is wonderful to have our friend, Ms. Herrera Beutler back here. We have not had her for a while. She has had the most excused absence of all time, but it is great to have her back.

Ms. HERRERA BEUTLER. Thank you.

Mr. COLE. And just to our witnesses, I have already told the chair this. At some point, I have to get up to go to a Republican leadership meeting. I will be coming back. It has nothing to do with your testimony. I have just been called away.

And I want to congratulate our chair for scheduling a perfectly timed hearing because we need something up here that brings us together, and this, you guys actually do that. So it is wonderful to see and, as always, the chair of the full committee.

Today, we have got our second budget hearing on the National Institutes of Health. And again, I want to thank the chair for having this hearing and inviting some of the Institutes and Centers we do not get to hear from as often as we should, and I associate myself with the remarks she made about that.

I look forward to learning more about the research being done and learning about the promising cures in the future. However, I would also be remiss if I did not recognize Dr. Francis Collins. I want to congratulate Dr. Collins on reaching an amazing accomplishment of leading the NIH for 10 years as Director. And he has heard me say it before, but he is clearly the best politician in Washington, D.C., if he can get appointed by both Barack Obama and President Trump. I mean, that is a pretty amazing span of appreciation for the manner in which he has led the NIH and a great deal of national confidence, obviously, in his ability and the wonderful team that he has assembled there and has been there for many, many years.

Obviously, Dr. Collins is an advocate for ground-breaking research done at the NIH and supported by NIH funding. And again, I have said it here, but the 4 years of sustained funding increases, which was, as the chair said, very bipartisan, owes a great deal to, frankly, our confidence in Dr. Collins as the leader of this Institute as well. And he has made the case up here for a lot of years as to why this was an important investment, and this committee, in a bipartisan fashion, has listened to that.

I want to highlight some of the work being done, frankly, at local universities in my district through the support of the NIH. Somehow they always seem to miss that when they announce some new cure. It never says funded by the NIH or awarded. So we need to work on that. Maybe require it when they get grants.

But working with colleagues at Oklahoma State University and the University of Oklahoma Health Science Center, researchers at the Oklahoma Medical Research Foundation are using a novel three-dimensional model made up of human tissue to study the now respiratory—and I will get this wrong. But is it syncytial virus? Well, I won't try it twice. Thank you. A virus that affects the lungs.

This virus is the leading cause of pneumonia worldwide. It can take a particularly heavy toll on children, infecting more than half in their first year of life and nearly 100 percent by age 2.

The virus is highly contagious, and for those with weakened immune systems from conditions like asthma, it can be dangerous and even deadly. These researchers hope to reveal what predisposes infants to severe infection and to create a launching pad for therapies down the line.

This lung in a petri dish model could prove to be valuable for studying other lung infections like flu, allergies, and asthma.

Another area of focus for the Oklahoma Medical Research Foundation is lupus. Lupus affects up to 1.5 million Americans, but it exacts a particularly heavy toll on African Americans, Hispanics, and Native Americans. Lupus is a chronic autoimmune disease that causes inflammation throughout your body.

An autoimmune disease is a condition in which your body's own immune system is responsible for the inflammation and breakdown of its own cells. The inflammation seen in lupus can affect various organs and tissues in the body, including one's joints, skin, blood, and internal organs. The disease can be severe and potentially life-threatening. It can cause permanent organ damage. Currently, there is no known cure for lupus.

Lupus remains a top 10 cause of death in African-American and Hispanic women between the ages of 15 and 45, and to understand more about it, scientists are conducting large-scale genetic analysis of thousands of lupus patients and thousands of healthy volunteers. They will focus on 25 genes that have been previously linked to the disease. Their goal is to identify the genetic culprits that disproportionately burden African Americans with lupus.

The study builds on the ground-breaking work that the Oklahoma Medical Research Foundation has already done in the lupus space, including discovery by one of its own researchers, Dr. Judith James, that anti-malarial medications can actually relieve and delay the symptoms of lupus. Because of Dr. James' discovery, these medications are now part of the standard treatment of care for many lupus patients.

There are countless stories like these of ground-breaking research taking part across the United States as a direct result of NIH funding. NIH fosters such ingenuity. A simple idea from one lone researcher can open an entirely new field of medicine and biomedical research. All Americans benefit from this research. Future generations will benefit from the untold promises from the research being done today.

Despite some of the controversy that can surround this bill, support for research at NIH has been broad, bipartisan, and been supported by leadership in the House and Senate alike.

I do not want to take up any additional time recognizing all the Institute Directors before us today because, quite frankly, I would rather hear from them about their exciting research. But I do want to thank each of you and your colleagues and those Institute and Center leaders who are not with us for their passion, dedication, and hard work.

I believe the work of the NIH has and will change the course of disease detection and treatment for generations to come. I hope Congress continues to be a supportive partner in these efforts.

Thank you, Madam Chair, for holding this hearing. I yield back my time.

Ms. DELAURO. Thank you very much, Congressman Cole.

I would just say I am not going to go into what they do, but I am so proud that Yale School of Medicine has one of the Clinical and Translational Science Awards. We are a hub, and there is amazing work that gets done there as well. So we thank you for that.

And with that, let me yield to the chairman of the Appropriations Committee, my colleague Congresswoman Nita Lowey.

The CHAIRWOMAN. And I thank my chair of this extraordinary committee for this hearing, which is so very, very important.

And I thank—I am sorry you are leaving, but I thank my good friend Mr. Cole for holding this hearing. There is no question that whether it is Chairman Cole or not Chairman Cole, there is bipartisan support for the outstanding work you are doing, and I really thank my good friend Chairwoman DeLauro for holding this hearing.

And I welcome our esteemed panelists, Dr. Tromberg, Dr. Pérez-Stable, Dr. Langevin, Dr. Austin, Dr. Brennan, and of course, Dr. Collins. I have been greeting you with a big smile for many, many years, and I really appreciate all that you and your team are doing.

Earlier in the year, however, the Trump administration submitted a budget that would cut the NIH by almost \$5,000,000,000. It is crystal clear that President Trump doesn't really understand the nature of this committee and how bipartisan it is and has no regard for the National Institutes of Health and the cutting-edge work you do to save lives, advance cures, improve the health of Americans.

Despite the President's heartless and misinformed efforts to gut the NIH, we have responded resoundingly. Unlike the President, my colleagues and I prioritize the health of all Americans. We are on track to invest billions more than the President would for our world-class National Institutes of Health.

Our House-passed fiscal year 2020 Labor, Health and Human Services, Education, and Related Agencies bill would provide \$2,000,000,000 more for the NIH, including a critical across-the-board increase for all the NIH Institutes and Centers. This would allow the NIH to better respond to scientific breakthroughs that result from astonishing foundational research done at the Institutes, such as those with us today.

We have the distinct pleasure to hear from several Institute Directors who are leading innovation in their respective fields. And there is so much innovation going on, Dr. Collins, I don't know if you just threw the numbers of the Institutes in a hat to try and pick which ones are here today, but I really look forward to hearing your remarks.

Not only will we hear about the encouraging advances achieved to date, but also the exciting innovations that are just over the horizon. We are talking about lifesaving achievements that, with our continued commitment and investment, could soon be on our doorstep, thanks to the NIH's extraordinary work.

So rest assured, the administration's attempt to slash your budgets will not stand. We remain committed to ensuring that you have the tools and the resources you need to deliver for the American people.

So I really do want to thank you, and I look forward to our discussion. Thank you all for everything you do just to improve lives.

Thank you.

Ms. DELAURO. Thank you.

We now will proceed to opening statements from the NIH panel. We have six witnesses today. So what we have done is to ask you to please offer 3 minutes of opening remarks. I am sorry to curtail the 5 minutes, but we want to get it all in, and then the opportunity to be able to ask our questions.

And Dr. Collins, again, welcome. Thank you for being here today. And you know the drill. The full testimony will be entered into the hearing record.

You are now recognized for 3 minutes. Dr. Collins.

Dr. COLLINS. Thank you.

Good morning, Chairwoman DeLauro, Ranking Minority Member Cole, distinguished subcommittee members. Yes, I am Francis Collins, Director now for slightly over 10 years of the National Institutes of Health.

On behalf of NIH, I want to thank the committee for your work on the fiscal year 2020 Labor, HHS funding bill that passed the House in June. We are really grateful for your ongoing and bipartisan support, and we were very pleased to host a visit by some of you last week.

Today, I am joined by the leaders of 5 of the NIH's 27 Institutes and Centers. Let me start by introducing Dr. Christopher Austin, who is Director of the National Center for Advancing Translational Sciences, NCATS. Like you, I am always impatient for basic research discoveries to be translated into new ways of combatting disease. To date, we have identified the molecular causes for more than 6,500 diseases, yet treatments exist for only about 500.

So addressing that gap requires translational research. One of my first initiatives upon becoming NIH Director was to ask Congress to create NCATS to speed this process, and you did, and here is the Director.

Next up is Patricia Flatley Brennan, who is next to me on my left, your right, Director of the National Library of Medicine, NLM. Like everything at NIH, NLM's activities are focused on innovation that advances biomedical research. One way it does this is through PubMed Central, a database that provides access to more than 5 million articles from biomedical journals.

Another is through ClinicalTrials.gov, the online catalogue of public and private clinical trials, which, by the way, is a great resource to share with any of your constituents looking to take part in medical research. That is where you can find those trials.

Now meet Helene Langevin, Director of the National Center for Complementary and Integrative Health, NCCIH, which this very week celebrated their 20th anniversary. In fact, it was you, this subcommittee, that established this Center back in 1999, citing the need for more scientific evidence on complementary health practices. That need remains great today.

Next let me introduce Dr. Eliseo Pérez-Stable, Director of the National Institute on Minority Health and Health Disparities, NIMHD. I think it is important for you to meet him for many rea-

sons, including at your April hearing, many of you asked about health disparities and the critical issue of maternal mortality.

Also part of today's distinguished lineup, at the end on my right, your left, Bruce Tromberg, Director of the National Institute of Biomedical Imaging and Bioengineering, NIBIB. His Institute engages engineers and other new types of investigators to push the innovation envelope to create smaller, faster, and less expensive medical technologies.

So, again, I thank you for this opportunity. I hope what you hear today helps explain why I am so excited to lead all of NIH's Institutes and Centers. Working together to encourage this next generation of researchers, I can assure you we will speed the path from discovery to health.

My colleagues and I will be happy to entertain your questions.
[The information follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Testimony before the
House Committee on Appropriations
Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

Francis S. Collins, M.D., Ph.D.,
Director of the National Institute of Health

September 25, 2019

Good Morning, Chairwoman DeLauro, Ranking Minority Member Cole, and distinguished Subcommittee Members. I am Francis S. Collins, M.D., Ph.D., and I am the Director of the National Institutes of Health (NIH).

I am joined by Christopher Austin, M.D., Director for the National Center for Advancing Translational Sciences (NCATS), Patricia Flatley Brennan, R.N., Ph.D, Director of the National Library of Medicine (NLM), Helene Langevin, M.D., Director of the National Center for Complementary and Integrative Health (NCCIH), Eliseo J. Pérez-Stable, M.D., Director of the National Institute on Minority Health and Health Disparities (NIMHD), and Bruce Tromberg, Ph.D., Director of the National Institute of Biomedical Imaging and Bioengineering (NIBIB),

I want to thank the Committee for its work on the Labor-HHS funding bill for FY 2020 that passed the House in June. We are grateful for your ongoing bipartisan support in helping NIH to continue our longstanding commitment to leading the world in biomedical research that will turn discovery into health.

Madam Chairwoman, I remember that, in April, you announced your intention to hold hearings with NIH Institute Directors who have not testified before the Subcommittee recently. We very much appreciate your and your colleagues' interest in having some of those Institutes and Centers (ICs) represented here today in effort to add some more detail to the very big picture that is biomedical research at NIH.

Unlike ICs that are primarily focused on research for specific diseases or disorders, many of which you have heard from often, our panel today comprises those that oversee a broad spectrum of research that is either disease agnostic, or improves the overall scientific and operational processes that lead to discoveries. It is an honor to be here today to talk about some of the research that is supported through these five ICs.

National Center for Advancing Translational Sciences (NCATS)

Nationwide, we have witnessed unprecedented advances in basic and fundamental science; however, the translation of research discoveries into treatments and interventions that improve human health in many instances is a slow and failure-prone process. The National Center for Advancing Translational Sciences (NCATS) was created to directly address this issue by improving the translation of discovery to health for the benefit of all biomedical research. NCATS is focused on improving the scientific and operational processes for refining and accelerating translation, the process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes.

For instance, through the flagship Clinical and Translational Sciences Award (CTSA) Program NCATS works collaboratively with more than 50 biomedical research institutions nationwide to improve clinical translation and to develop a cadre of trained investigators through sustainable translational science career development pathways. In the Trial Innovation Network (TIN), NCATS is developing, demonstrating the effectiveness of, and disseminating scientific and operational innovations to dramatically increase the efficiency and effectiveness of clinical

studies. With the participation of the CTSA Program hubs, Trial Innovation Centers, and Recruitment Innovation Center, the TIN works to understand and mitigate the delays and failures that can result in enormous losses to the health and lives of patients, the careers of investigators, and the advancement of science and medicine.

As another example, now in its tenth year, the Toxicology in the 21st Century (Tox21) program is a four-Federal agency collaboration among NCATS, the National Toxicology Program at NIH's National Institute of Environmental Health Sciences (NIEHS), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). Working to identify pre-clinical translational failure that results from unanticipated adverse effects of a new drug in humans, Tox21 fosters the systematic understanding of toxicity and the development of new testing systems. Tox21 researchers have developed new testing paradigms, a public database of more than 100 million test results on over 10,000 drugs and chemicals, and computational algorithms that are remarkably accurate in predicting the potential toxicity of a new compound. These publicly available data are now beginning to inform regulatory decisions about safety.

Additionally, NCATS is placing priority in advancing and accelerating treatments for rare diseases. There are about 7,000 diseases officially defined as "rare," or affecting fewer than 200,000 people in the United States; only a few hundred of these diseases have any approved treatment. Added together, rare diseases are anything but rare; they affect 25 million people in our country alone, and approximately 50 percent of rare disease patients are children. Families generally must cope with a years-long odyssey to a correct diagnosis, only to find that 95 percent of the time there is no effective available treatment. These too-often disabling and fatal diseases are devastating and costly for patients, their families, and the Nation.

NCATS is applying its collaborative translational science model to transform understanding, diagnosis, and treatment of rare diseases. NCATS' fundamental approach is to shift from considering each rare disease in isolation to identifying and developing treatments for rare diseases based on their commonalities. NCATS invests resources and expertise at the points where research is most difficult and therefore often abandoned.

Most rare diseases are genetic, caused by "misspellings" in DNA that are passed from one generation to the next. Advances in gene delivery and gene editing have recently re-invigorated gene therapy as a potential approach to treating genetically-based diseases. Unlike small molecule drugs, genes cannot enter cells, so they need to be transported in the body and into the diseased cell type by a "vector" carrier. While effective, this requirement for a vector greatly increases the experimental, regulatory, safety, clinical complexity, and cost of gene therapy, since both the carried gene and the vector are different in every development program. This significantly hinders gene therapy being expanded or "scaled up" to address the many diseases that potentially could be treated. To tackle this problem, and thus simplify gene therapy and make it more efficient and effective, NCATS is developing a Collaborative Rare Disease Platform Vector Gene Therapy Trial (PaVe-GT) program. Viral vectors will be well-characterized for their capacity and safety as gene delivery vehicles and tested as platforms to carry a variety of genes to treat multiple diseases. Initially, NCATS will support the testing of vectors as gene delivery vehicles for the treatment of at least three rare genetic diseases that share a therapeutic target tissue or cell type. If successful, NCATS will expand this strategy to

provide rare diseases researchers with a palette of vectors to treat many, and potentially all, rare genetic diseases.

National Library of Medicine (NLM)

Through its cutting-edge research, information systems, collections, and training programs, NLM plays an essential role in catalyzing basic biomedical science and data-driven discovery. NLM acquires, organizes, curates, and delivers up-to-date biomedical information across the United States and around the globe. NLM makes research results available for translation into new treatments, products, and practices; provides decision support for health professionals and patients; and aids disaster and emergency preparedness and response.

NLM is a leader in data science and open science, including the acquisition and analysis of data for discovery and the training of biomedical data scientists. As biomedical research becomes increasingly digital, NLM is expanding its data science and biomedical informatics research programs to improve access to digital knowledge assets, including research and bibliographic data, software used to generate or analyze research data, and models and workflows used in research. Making such materials findable, accessible, interoperable, and re-usable (FAIR), as well as attributable and sustainable, accelerates science, broadens opportunities for collaboration, enhances accountability, and increases the return on investments in research for research participants, science, and society.

NLM continues to expand the quantity and range of high-quality information readily available to scientists, health professionals, and the public. Every day, NLM serves more than 5 million users, receiving up to 15 terabytes of new data, adding value by enhancing data quality and consistency, and integrating new data with other information in NLM databases. NLM responds to millions of inquiries per day from individuals and computer systems and provides more than 115 terabytes of information, including more than 5.1 million published articles in PubMed Central (PMC), NLM's free full-text archive of biomedical and life sciences journal literature. On a typical day, more than 2.5 million users download articles from PMC.

NLM also maintains the Sequence Read Archive (SRA), the largest publicly available data repository, which includes more than 9 million records of next-generation genomic sequence data. Each month, 100,000 users download more than 2 petabytes of data. To improve access to and utilization of this data, NLM has uploaded the entire SRA data to two commercial cloud partners as part of NIH's STRIDES (Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability) Initiative. This approach enables scientists, industry, and the general public to bring large-scale computing power to the data for novel scientific discovery.

National Center for Complementary and Integrative Health (NCCIH)

Through rigorous scientific investigation, the National Center for Complementary and Integrative Health (NCCIH) carries out its mission to define the safety and effectiveness of complementary and integrative health approaches – a group of practices and products that originate outside of conventional medicine but are typically used in conjunction with

conventional medicine. This diverse group of health practices includes natural products, such as dietary supplements, plant-based products, and probiotics, as well as mind-body approaches, like yoga, massage therapy, meditation, mindfulness-based stress reduction, spinal manipulation, and acupuncture. Integrative health care seeks to bring conventional and complementary approaches together in a safe, coordinated way.

Consumers often use complementary health approaches without understanding whether they work, or if they are safe, and without talking with a health care provider. Much of the information available to consumers is promotional, and not rooted in peer-reviewed, scientific evidence. NCCIH works to expand and share science-based evidence regarding complementary and integrative health approaches to inform health care decision-making by consumers, health care professionals, and policymakers.

The support of health and wellness is a priority of NCCIH. A small but growing evidence base suggests a potential benefit of complementary health approaches for the purposes of wellness, health promotion, and disease prevention. For example, music has been associated with several positive benefits. Music may enhance child development, improve adult function and well-being, and optimize the quality of life during aging. Many studies have shown that music may ameliorate the symptoms of a broad range of diseases and disorders that occur throughout the lifespan. However, more research is needed to determine where music therapy, in its many forms, can be beneficial and under what conditions. The exciting potential of this research has led to the formation of a trans-NIH Working Group, co-led by NCCIH. Together this working group developed a funding opportunity entitled “Music and the Brain: Research Across the Lifespan.” A set of 15 new awards has just been made. The aim of this initiative is to increase understanding of how music can affect health, with an emphasis on what happens at the neuronal level, and potential clinical applications.

According to a 2012 National Health Interview Survey (NHIS), Americans are spending approximately \$30.2 billion per year on complementary approaches to improve their overall health, manage symptoms of chronic diseases, and/or counter the side effects of conventional medicine. Pain is one of the leading reasons Americans turn to complementary health approaches. Current drug-based treatment options are only partially effective and can have serious side effects.

Responding to this need, NCCIH supports safety and efficacy trials of nonpharmacologic pain management approaches, as well as research on the basic biology of pain and pain processing in order to understand how these approaches can influence pain. NCCIH’s role in the HEAL (Helping to End Addiction Long-term) Initiative builds upon the leadership they have demonstrated in supporting research on nonpharmacologic treatments and pragmatic trials embedded in health care system delivery. NCCIH is leading two HEAL programs – Behavioral Research to Improve Medicated Assisted Treatment (BRIM) and Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing (PRISM).

As another example, NCCIH along with other NIH, Department of Defense (DoD) and Department of Veterans Affairs (VA) partners launched the NIH-DoD-VA Pain Management Collaboratory (PMC) in 2017. The PMC focuses on nonpharmacologic approaches for pain

management and related conditions in military and veteran populations. The PMC currently funds 11 pragmatic clinical trial research project grants and a resource coordinating center, totaling approximately \$81 million over six years, with the NCCIH contributing more than half of these funds. The studies will not only show if specific nonpharmacologic approaches are effective for pain management, but also how they can be integrated into a healthcare system. This initiative may lead to new pain management practices within the DoD and VA and support the use of nonpharmacologic approaches for pain management in the general population.

National Institute on Minority Health and Health Disparities (NIMHD)

I know that many Members of the Subcommittee have interest in examining individual factors and systems in which we live, learn, work, and play that influence health status. The National Institute on Minority Health and Health Disparities (NIMHD) leads scientific research to improve minority health and to reduce health disparities. That research has evolved from a basic descriptive understanding of what health disparities are and who is most affected to discovering the complexity of factors involved in health and its outcomes. NIMHD works to transform the field of minority health and health disparities by building on evidence-based advances in promising areas such as genomics, behavioral and social science, and health information technology that could be beneficial in improving the health of racial and ethnic minority populations, people living in rural communities, individuals of low socioeconomic status, and sexual and gender minorities who often experience poorer health and greater disparities in health outcomes.

In the United States, it is estimated that 700 women die yearly from pregnancy and delivery complications,ⁱ and approximately 50% of these deaths are preventable.ⁱⁱ Maternal mortality rates (MMR) have increased from 17 deaths per 100,000 births in 1990 to 26 deaths per 100,000 births in 2015. Additionally, significant racial disparities in pregnancy-related mortality (PRM) persist. Black and American Indian/Alaska Native women experience the highest rates of PRM, at a rate that is three to four times higher than that of White women. NIMHD is funding research to examine postpartum hemorrhage (PPH), a leading contributor to maternal morbidity and mortality in the United States. Researchers aim to investigate racial and ethnic differences in PPH management (e.g., medications administered, blood transfused, surgical interventions used) and the timing of those interventions as a way of identifying more targeted interventions. NIMHD will examine how environmental, sociocultural and behavioral factors influence health outcomes in PRM, including the importance of patient-clinician communication, implicit and explicit biases in care, and the quality of health care.

Another example of NIMHD's work includes studying the interaction between epigenetic and biobehavioral determinants of preterm birth in African American women. Recent findings discovered that DNA methylation in the SLC9B1 gene in late second and early third trimesters can predict fetal intolerance of labor (FIL) or fetal distress at delivery, the most common indication for emergency Caesarean section, which is associated with increased risk of an insufficient supply of oxygen reaching the unborn baby and excessive acidity in the blood following deliveryⁱⁱⁱ. These findings could set the basis for a diagnostic test to identify pregnant women at elevated risk for FIL well in advance of delivery.

To highlight another area, NIMHD established the Surgical Disparities Research Initiative to support investigative and collaborative research focused on understanding and addressing disparities in surgical care and outcomes in minority and health disparity populations. Despite overall improvements in surgical care, surgical disparities remain a persistent concern in the healthcare system, and an understudied issue in health disparities research.

Disparities in surgical care by race and ethnicity are partly due to a lack of standardized quality indicators to measure surgical disparities and access to surgical care. The Developing Disparities-Sensitive Surgical Quality Metrics is a project funded by NIMHD aimed at developing a standardized disparities sensitive metric on quality of surgical care that can be implemented in various hospital settings.

Cultural difference or incongruity is a factor often associated with the patient-clinician experience and relationship. NIMHD is funding a clinical trial involving eight academic medical centers to evaluate the effectiveness of the Provider Awareness and Cultural Dexterity Toolkit for Surgeons (PACTS), to assess surgical residents' knowledge, attitudes, and cross-cultural skills in caring for patients of diverse cultural backgrounds.

National Institute of Biomedical Imaging and Biomedical Engineering (NIBIB)

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) is now in the middle of its second decade of significant progress in developing novel biomedical technologies to help diagnose, treat, and prevent illness. NIBIB's vision of improved health for all Americans is driven by the convergence of engineering and the physical and life sciences.

Recent scientific advances are giving us new tools to tackle challenging health problems. Sophisticated imaging techniques allow us to peer into the human body with pinpoint accuracy and even eliminate or repair unhealthy tissue. Developments in bioengineering promise to enhance the body's natural ability to recover from injury and disease, aided by a new generation of biotherapeutics. Transformative technologies are also being made possible with new types of materials and electronics. As one example, NIBIB-supported researchers created a small, flexible ultrasound patch that can be worn like a band-aid to accurately monitor blood pressure. The idea to utilize ultrasound technology in a wearable device is a new approach that could lead to other avenues for monitoring and diagnosing illness.

Flexible electronics, ink-jet printable materials, and harnessing the increasing computing power of smartphones are a few of the advances that will enable future discoveries and help propel them to become useful tools for medical practitioners and individuals. NIBIB's Discovery Science and Technology (DST) Program is helping to drive scientific progress and lead a path toward the future of medicine where faster, better, less costly approaches are more broadly applicable. In a test case of this type of technology, researchers designed a sensor platform to detect a protein biomarker (HER-2) for diagnosing one type of breast cancer. This test uses electrochemical detection, a method that measures electric currents that are generated from reactions in the test compounds. The benefits of the device are numerous: it can be manufactured for 25 cents, gives results in 15 minutes, and of great importance to patients, it uses a small blood plasma sample instead of tissue, thus eliminating the need for painful biopsy.

NIBIB-supported research in health informatics technology (HIT) is also building toward practical, patient-centered applications such as using data to help doctors make clinical decisions, developing technologies to monitor a patient's treatment in their own home, and improving medical images with the next generation of intelligent data analysis tools and support systems. Telemedicine and mobile health technologies are transforming healthcare delivery, with the potential to provide broader access for a range of illnesses to patients in their own homes or a nearby clinic. One experimental method of using telemedicine to help monitor patients in their own home is a system to detect a dangerous drop in white blood cells in patients receiving chemotherapy. NIBIB researchers developed a prototype tabletop device designed to be used easily at home, which operates by taking a video of blood moving through extremely small capillaries at the base of the fingernail just below the skin. From the video, the device can count the number of white blood cells, detecting a reduction in the normal number of white cells expected in just one minute – helping already compromised patients to avoid contracting infectious disease, hospitalization, and even death.

In closing, Madam Chairwoman and Members of the Subcommittee, I hope that our being here today will help to cultivate even further your knowledge of the great work being done at NIH. This is a time of remarkable opportunity for translating scientific discovery from numerous domains into improvements for Americans' health. On behalf of the panel here today, I thank you for your strong, consistent, and bipartisan support for investments toward making and applying those crucial discoveries.

This concludes my formal remarks. My colleagues and I welcome your questions.

ⁱ Centers for Disease Control and Prevention, **Racial/Ethnic Disparities in Pregnancy-Related Deaths — United States, 2007–2016 (September 6, 2019)**. https://www.cdc.gov/mmwr/volumes/68/wr/mm6835a3.htm?s_cid=mm6835a3_w

ⁱⁱ Main & Menard, 2013. **Maternal mortality: time for national action**. *Obstet Gynecol*. 2013 Oct;122(4):735-6 PubMed ID: 24084528.

ⁱⁱⁱ Kumar PL, James PF. **Identification and characterization of methylation-dependent/independent DNA regulatory elements in the human SLC9B1 gene**. *Gene*. 2015 May 1;561(2):235-48. doi: 10.1016/j.gene.2015.02.050. Epub 2015 Feb 19. PMID: 25701605; PMCID: PMC4361323.

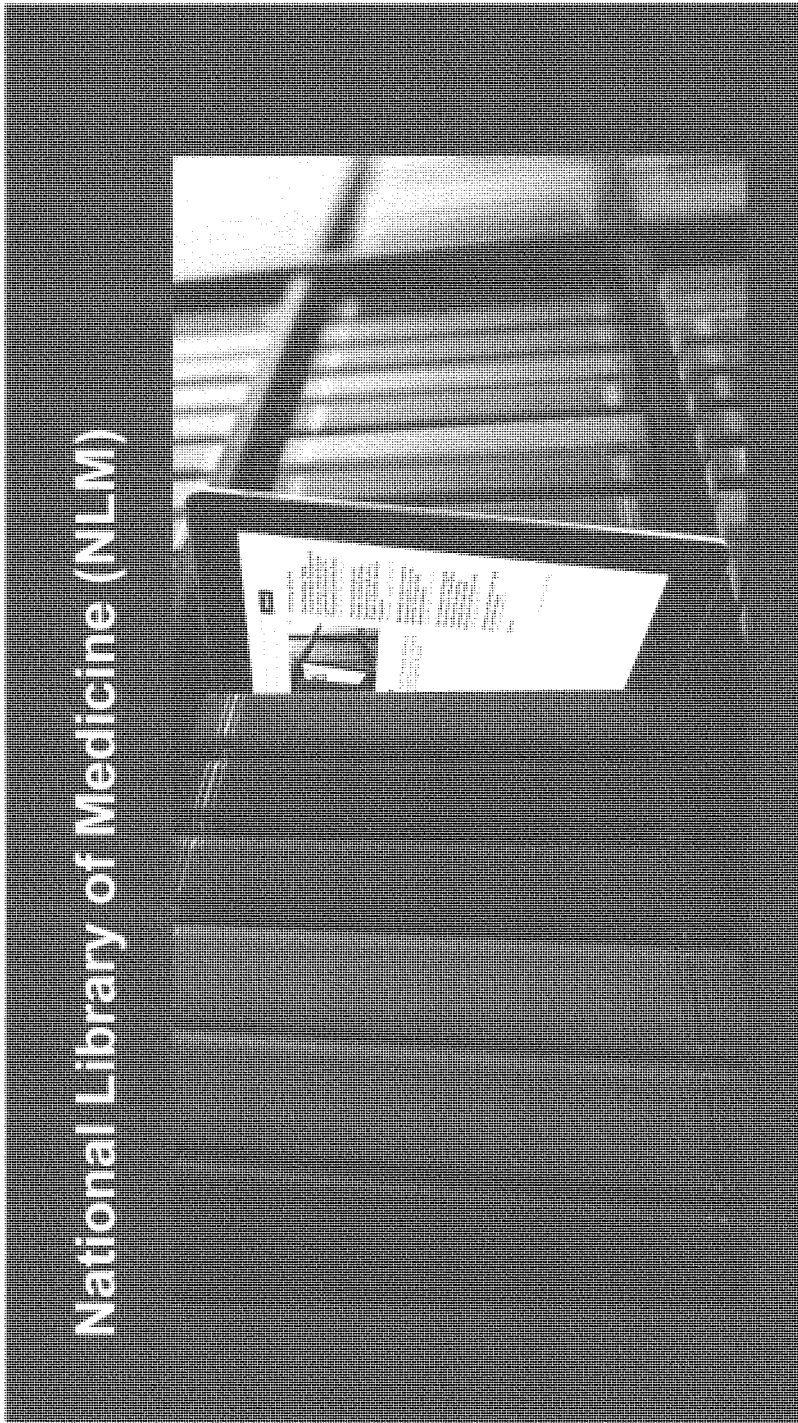
Investments in Medical Research at Five NIH Institutes & Centers
 Francis S. Collins, M.D., Ph.D.
 Director, National Institutes of Health

House Labor/HHS Appropriations Subcommittee
 September 25, 2019



National Center for Advancing Translational Sciences (NCATS)





National Library of Medicine (NLM)

National Center for Complementary and Integrative Health (NCCIH)

NCCIH at 20
A Catalyst for Integrative
Health Research

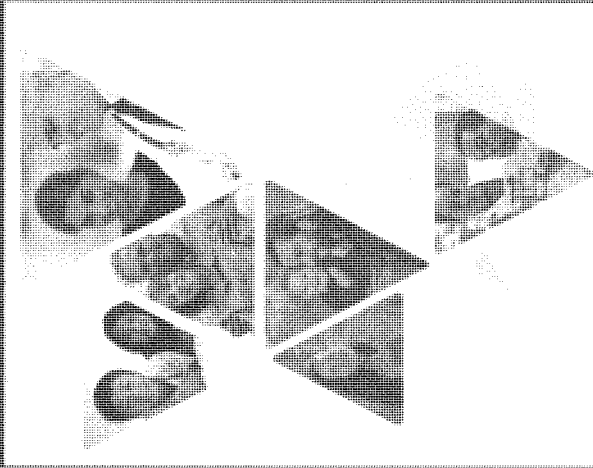
20th Anniversary
Celebration of the National
Center for Complementary
and Integrative Health

September 23, 2019

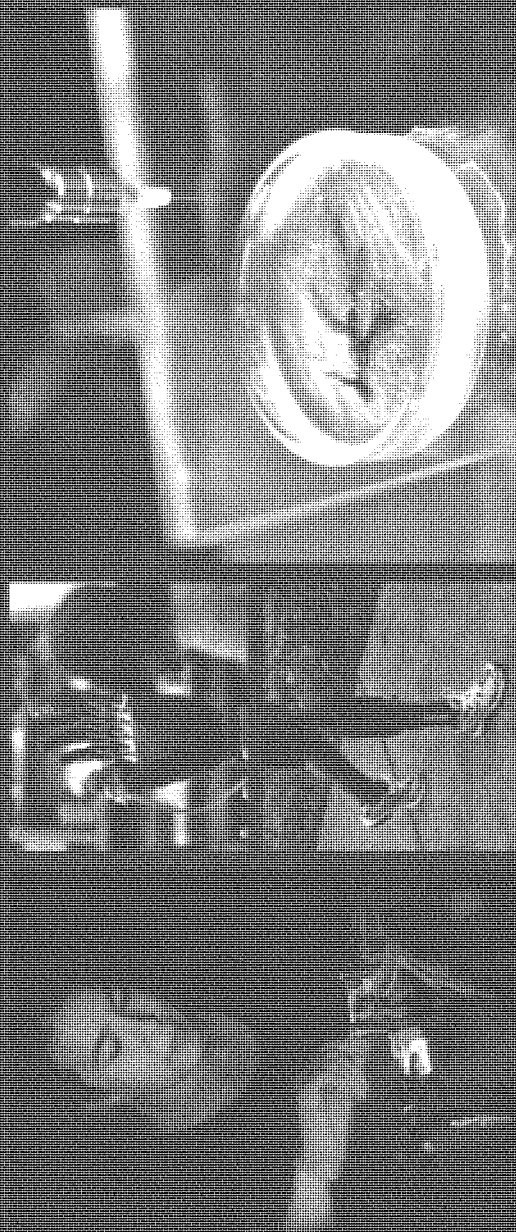
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National Institute on Minority Health and Health Disparities (NIMHD)



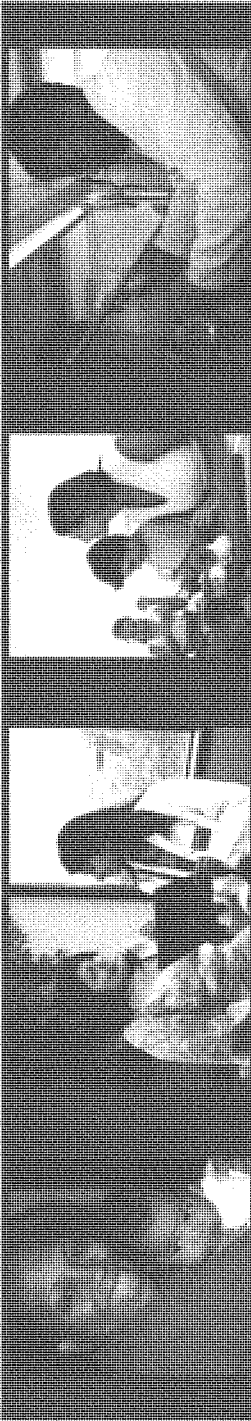
National Institute of Biomedical Imaging and Bioengineering (NIBIB)



All of NIH:

Speeding Our Path to the Future



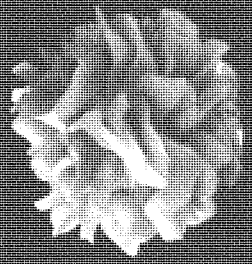


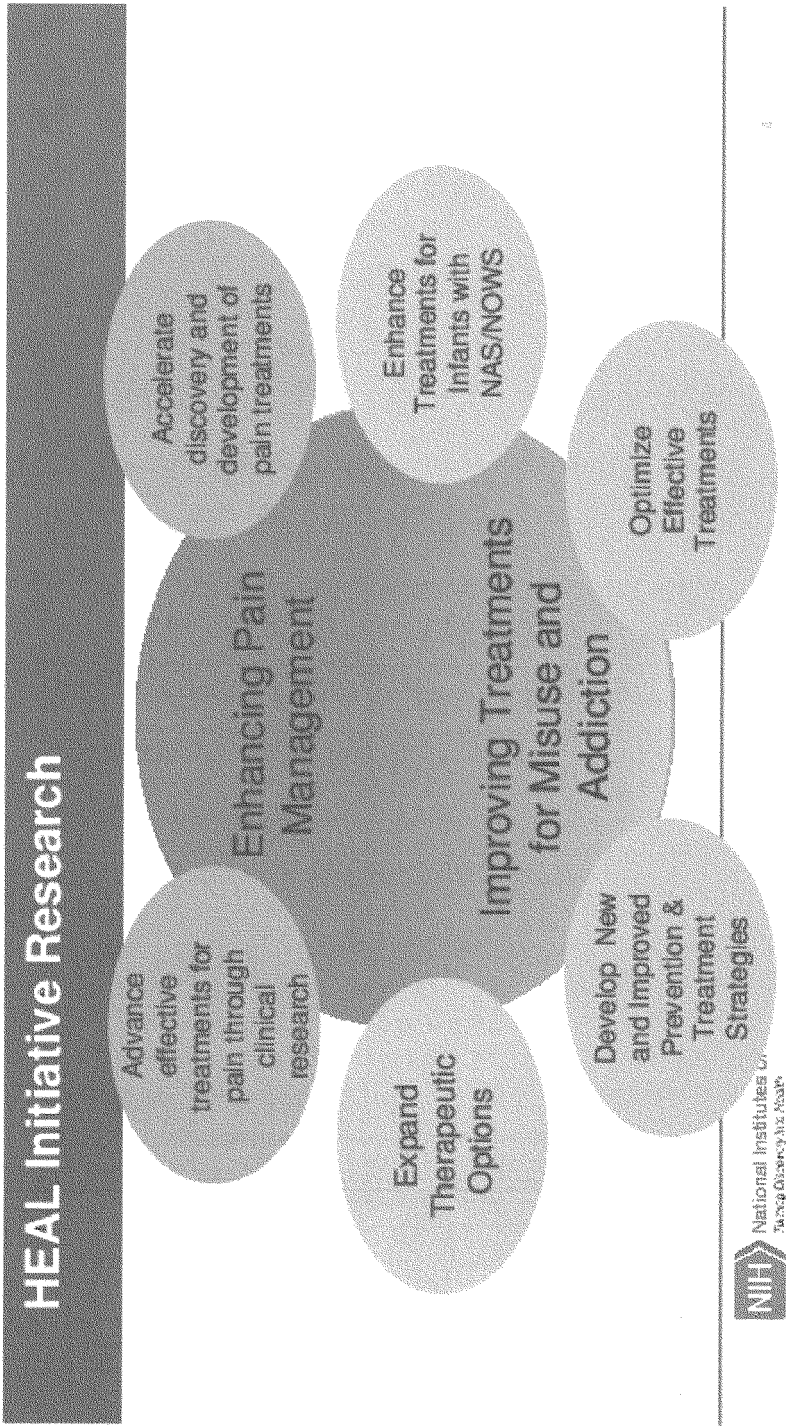
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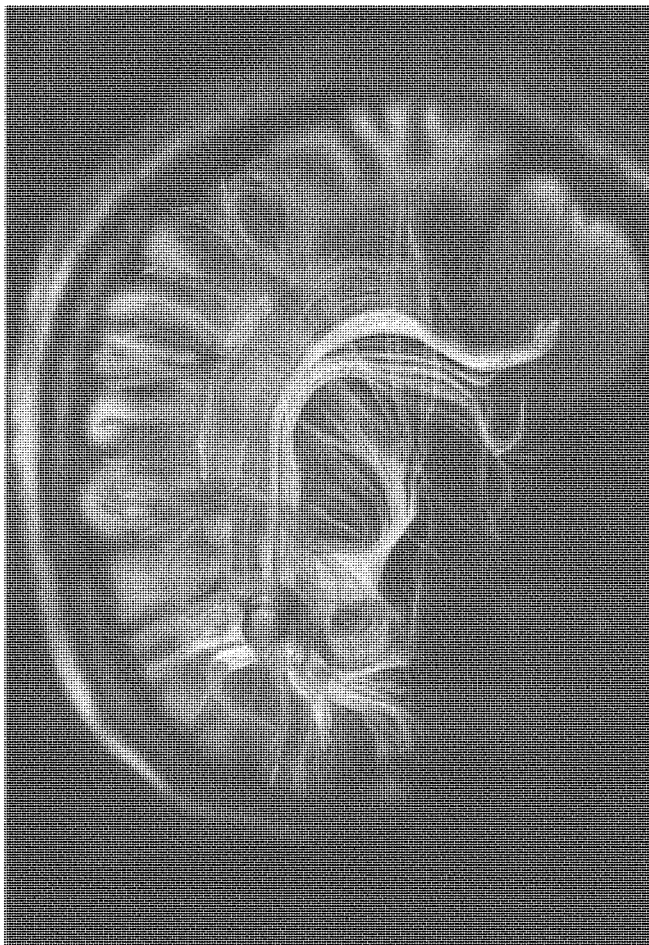
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The NIH BRAIN Initiative



Ms. DELAURO. Thank you very, very much, Dr. Collins, and for being so succinct.

Dr. COLLINS. It is unusual for me, I know. [Laughter.]

Ms. DELAURO. Please now let me just recognize Dr. Tromberg. Thank you again. Your full testimony will be entered into the hearing record. You are recognized for 3 minutes.

Dr. TROMBERG. Thank you.

Madam Chairwoman and members of the subcommittee, it is an honor to participate in your hearing and represent the thousands of talented engineers and physical scientists across the country who are developing innovative new technologies to improve human health. I have only been Director of the NIBIB for about 9 months, but I have spent 30 years pioneering new optics and photonics technologies and training students as a professor of biomedical engineering and surgery at the University of California.

NIBIB's mission is to transform through engineering the understanding of disease and its prevention, detection, diagnosis, and treatment. We support cutting-edge research that can be applied to a broad range of biomedical healthcare problems by building strong partnerships with industry, academia, Federal agencies, and every NIH Institute and Center. Our programs lead to better, faster, and less costly ways to advance technologies from blackboard to benchtop to bedside.

NIBIB supports about 1,000 grants each year in four major technical areas—computation and artificial intelligence, engineered biology, sensing and imaging, and advanced therapeutics. One of our most innovative and practical sensing platforms has been developed to address the widespread problem of food allergies.

We all know that eating out can be an anxious, even life-threatening challenge for millions of Americans. Recognizing this widespread public health problem, researchers have developed a rapid, quantitative point-of-care technology. It is small enough to fit on a keychain and can test for common allergens such as gluten, milk, or nuts at your table in less than 10 minutes.

Small personal sensor technologies are also helping drive the development of new personalized imaging platforms. To help address the challenging problem of breast cancer detection painlessly and without x-rays or contrast agents, researchers are using invisible laser light pulses that are one-billionth of a second in duration to create ultrasonic vibrations deep inside breast tissue. As these sound waves are detected by sensors on the skin surface, 3-D images of breast tissue structure and function are formed that can be used for tumor detection, diagnosis, and guiding therapies.

In the same way that advanced imaging technologies have practically eliminated the once common practice of exploratory surgery, new technologies are revolutionizing brain surgery so it can be done without scalpels. The approach uses special ultrasound transducers placed around the head that are controlled to target structures deep inside the brain. Treatments are under development for movement disorders such as essential tremor, as well as delivering therapeutic drugs to tumors without collateral damage.

This is a brief snapshot of how spectacular advances in biomedical technologies are dramatically changing our world. It is exciting to be part of this rapidly growing interdisciplinary commu-

nity of innovators. We are committed to working together with our colleagues in every NIH Institute and Center to better engineer the future of health for all Americans.

Thank you for your time, and I look forward to the opportunity to answer questions.

[The information follows:]

PREPARED STATEMENT OF BRUCE TROMBERG, PH.D.
DIRECTOR, NATIONAL INSITUTE OF BIOMEDICAL
IMAGING AND BIOENGINEERING

Ms. Chairwoman and Members of the Subcommittee: I am pleased to provide this statement highlighting the excellent programs of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) of the National Institutes of Health (NIH).

The mission of NIBIB is to improve human health by leading the development of biomedical technologies and accelerating their application. NIBIB supports research that integrates engineering with the physical and life sciences to develop new technologies that can be applied to a broad range of biomedical and health care problems. Building partnerships with industry, academia, and other federal agencies is a high priority for the institute. A few examples from the many exciting NIBIB-funded research efforts that are leading to better, faster, and less costly ways to advance public health are shared in this testimony.

ON THE SPOT FOOD ALLERGY TESTING

Eating out can be a challenge for people with allergies. Diners must rely on knowing what ingredients contain the allergens they must avoid, and on restaurants to serve dishes that exclude them. Recognizing this widespread public health problem, researchers have developed a system called integrated exogenous antigen testing (iEAT). The purpose of the iEAT system is to give those who suffer from food allergies a rapid, accurate device that allows them to personally test foods in less than 10 minutes. The

device is small enough to fit on a keychain and can test for common allergens such as gluten, milk, or nuts. The device contains a disposable testing chamber, so once a test is completed the chamber can be replaced and the device used again. After developing and testing a prototype of the device, the research team granted a license to a local start-up company to make iEAT commercially available. In the future the device could be adapted to test for other allergens or substances.

FOCUSED ULTRASOUND FOR SURGERY

Using a new ultrasound technique, researchers have developed an entirely non-invasive tool for brain surgery. This new approach uses targeted sound waves to manipulate the brain without opening the skull. This technique offers the potential to treat essential tremors—a symptom of Parkinson’s disease—and other movement disorders. Other applications include opening the blood brain barrier without damaging tissue to allow medications used to treat brain tumors or other neurological diseases to enter the brain.

CLEARING OUT BLOOD CLOTS

A blood clot that forms in the deep veins of the legs is called deep vein thrombosis and can be quite painful, and even fatal if a clot dislodges from the wall of the vein and travels to the heart or lungs. Currently, intravascular treatments use devices

inserted into the vein to trap clots, but they have limitations including damage to the blood vessel wall. In some patients, clot thinning medication is required, which can have a range of side effects. A new approach to overcome these limitations uses a surgical tool that is inserted into a vein and directs ultrasound waves directly at clots to break them up into tiny pieces. It is targeted and therefore minimizes damage to blood vessels; and because the broken pieces are tiny, patients do not need to use blood thinning medication following the procedure. In addition to using ultrasound, researchers are adding injectable microbubbles that vibrate when exposed to the ultrasound waves. This helps to further break up the clot. This tool is portable and is estimated to cut the declotting procedure time by more than half, from 10 hours to four hours. So far, the tool has only been tested in synthetic blood vessels, and more study is needed to bring this treatment to patients.

NANOVACCINES WEAPONIZED TO BATTLE TUMORS

A new vaccine designed to stimulate a multi-pronged immune response can stimulate the immune system to specifically attack a tumor, while simultaneously inhibiting the suppression of the immune system, which often occurs in people with cancer. The researchers also developed a way to shrink the vaccine molecule so that it can more easily reach the parts of the immune system to activate it. Using colon cancer that had spread to the lungs as a test case for this approach, the nanovaccine successfully blocked lung tumor growth in a mouse model. Further testing revealed that mice receiving the nanovaccine had a significant increase in a type of immune cell that can

target cancerous cells. Another potential benefit of this approach is that it mounts an anti-tumor immune response that circulates through the system, and therefore is particularly valuable for finding and inhibiting metastatic tumors growing throughout the body.

SOLVING A COMMON HEART DISEASE WITH ENGINEERING

Ischemic cardiovascular disease is a result of impaired blood circulation to tissues and organs and is the leading cause of death and disability in the U.S. Damage to small blood vessels is difficult to treat and can result in heart failure, stroke, or other arterial diseases. To address this problem, researchers developed a way to grow new blood vessels using 3D printed patches. The specially designed patches are seeded with cells and implanted into damaged areas. Once implanted, the patches induced the growth of new blood vessels. This early stage, basic research is an example of interdisciplinary teams including engineers, biologists, and clinicians combining their expertise and collaborating to solve health problems.

ADVANCES FROM NIBIB LABORATORIES

NIBIB's growing Intramural Research Program (IRP) supports a range of discovery including investigators working to create optical imaging technologies that provide unprecedented high resolution and speed to study living cells in real time. Others create "theranostic" imaging probes—based on nanomaterials—that combine therapeutic

and diagnostic capabilities to improve early diagnosis, monitor therapeutic responses, and guide drug discovery and development.

In one example, researchers developed a new radiotracer to help diagnose prostate cancer. Prostate cancer is the fifth leading cause of death worldwide and is especially difficult to diagnose, particularly early on. While prostate cancer is relatively easy to treat in its initial stages, it is prone to metastasis and can quickly become deadly. The research team developed a radiotracer that could identify prostate cancer at all stages. This new tracer is one of the first dual-receptor target tracers, which target more than one biomarker, to be studied in humans. This new method improves on the current practice that can lead to many false positive results and cause the patient to undergo unnecessary treatments or painful biopsies. A successful Phase I clinical trial with a small group of patients to establish safety and identify any possible side effects was recently completed.

CONCLUSION

Advances in technology are catalyzing the development of solutions to previously intractable disorders and improved approaches to biomedical research. As these examples illustrate, this type of research requires many disciplines to work together. This integration of disciplines is what defines NIBIB's approach. NIBIB is Engineering the Future of Health to solve major biomedical challenges that will improve the health of all Americans.

Ms. DELAURO. Thank you very much.

I want to get hold of this mechanism. I am lactose intolerant. It is really unbelievable going to a restaurant and trying to figure out what is in what. So we will speak. [Laughter.]

Ms. DELAURO. Dr. Langevin, welcome. Thank you for being here today, and again, your full testimony will be entered into the hearing record. You are recognized for 3 minutes.

Dr. LANGEVIN. Madam Chairwoman, Ranking Committee Member Cole, and distinguished members of the committee, I am pleased to talk with you today about the exciting work supported by the National Center for Complementary and Integrative Health, or NCCIH.

My clinical training is in internal medicine, but I also have had a longstanding interest in complementary treatments and practices like acupuncture and yoga that originated outside of conventional medicine but are increasingly integrated into mainstream healthcare. The most common reason Americans turn to complementary and integrative practices is chronic pain, and NCCIH devotes 40 percent of its portfolio to research related to pain and pain treatment.

This research is now part of the HEAL Initiative, which stands for Helping to End Addiction Long-term, an aggressive trans-agency effort to speed scientific solutions to the national opioid crisis, which is fueled by the highly addictive opioids that are used to manage pain.

There is an urgent need for improved pain management, including nonpharmacological methods and treatments. NCCIH supports research on behavioral strategies for managing chronic pain, improving adherence to the medical treatment of opioid use disorders, and reducing the craving to take opioids.

Another important area of focus at NCCIH is natural products. Nearly one in five adults in the U.S. use botanicals and other dietary supplements such as fish oil and probiotics. Adverse events related to dietary supplements are common, especially when used in combination with drugs, and are estimated to contribute to 23,000 emergency room visits each year. NCCIH reports rigorous research on the biological mechanisms, benefits, and potential harms of natural products to improve the knowledge available to healthcare providers and patients.

Integrative health means integration, but not just of complementary and conventional treatments. It also means integration of health as a whole. Our current biomedical research model is superb in advancing the specialized treatment of organ-specific diseases with increasing precision.

There is also a need for a better understanding of health as a process involving the whole person. We know that a combination of poor diet, sedentary lifestyle, and chronic stress leads to major chronic conditions, including cardiovascular disease, diabetes, degenerative joint disease, chronic pain, and depression that tend to occur together in the same people.

Behavioral methods, such as simple relaxation techniques, especially when taught early in life, can equip patients with tools to help themselves with stress, pain, and sleep for the rest of their

lives. And a good night's sleep does wonders to stay motivated to eat better and exercise.

Advancing research on whole person health is imperative if we want to improve the overall health of our society.

Thank you, and I look forward to your questions.

[The information follows:]

PREPARED STATEMENT OF HELENE LANGEVIN, M.D.
DIRECTOR, NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE
HEALTH

The mission of National Center for Complementary and Integrative Health (NCCIH) is to define, through rigorous scientific investigation, the safety and effectiveness of complementary and integrative health approaches, which are a group of practices and products that originate outside of conventional medicine. This diverse group of health practices includes natural products such as dietary supplements, plant-based products, and probiotics, as well as mind-body approaches such as yoga, massage therapy, meditation, mindfulness-based stress reduction, spinal manipulation, and acupuncture. According to a 2012 National Health Interview Survey (NHIS), Americans are spending approximately \$30.2 billion a year on complementary approaches to improve their overall health, manage symptoms of chronic diseases, and/or counter the side effects of conventional medicine. However, the scientific research base surrounding the safety and efficacy of these practices is limited. Therefore, NCCIH is committed to providing the American public with valuable information about these practices, while also investigating how specific complementary approaches can be integrated into conventional medical care.

**EXPLORING NONPHARMACOLOGIC APPROACHES FOR PAIN
MANAGEMENT**

NCCIH is devoting significant resources to understand the basis of pain and how complementary and integrative health approaches can be utilized in pain management. Pain is a major public health problem and is the most common reason Americans turn to complementary and integrative health practices. Data from the 2012 NHIS found that an estimated 25.3 million adults in the U.S. (11.2 percent) experience daily pain with nearly 40 million adults (17.6 percent) experiencing severe levels of pain. The use of highly addictive opioids as a primary pain management strategy in the U.S. is helping to fuel the growing opioid misuse epidemic. Improved strategies for pain management may lead to a decreased reliance on opioids for patients suffering from pain. NCCIH supports research to better understand the biologic mechanisms of pain and to identify effective nonpharmacologic approaches to reduce the duration and intensity of pain.

Research supported at NCCIH is focused on understanding the role of the brain in perceiving, modifying, and managing pain, with the long-term goal of improving clinical management of chronic pain through the integration of pharmacologic and nonpharmacologic approaches. Recently, scientists discovered a new class of sensory nerve cells that respond to high-threshold (intense) mechanical stimuli, such as hair pulling. This work provides insights into how our bodies encode and transmit pain sensations. Another study mapped the regions of the brain activated during pain to establish a “pain signature” and found that specific regions of the brain respond to pain intensity, while other regions mediate the psychological effect, and yet another region showed increased activity related to pain relief. This work not only provides insights

into how pain is interpreted, but could lead to the development of new methods to detect, quantify, or target pain.

NCCIH-supported research is also advancing understanding of the mechanisms of action of mind and body interventions and determining their effectiveness for treating pain. One study investigated the effect of acupuncture on carpal tunnel syndrome and found that it affected activity within brain pain centers, decreased associated pain symptoms, and improved overall wrist function. Mindfulness meditation is another promising area of research. Numerous studies have shown that mindfulness meditation helps relieve pain, but the mechanism through which meditation exerts this effect is not well known. New study results demonstrate that mindfulness meditation activates the same region of the brain as opioids; however, it reduces pain independently of opioid neurotransmitter mechanisms. These results suggest that greater pain control could be achieved through the combination of mindfulness meditation and opioid-signaling-induced pharmacologic approaches. NCCIH-supported research has also shown that mindfulness-based stress reduction and cognitive behavioral therapy can improve functioning and reduce chronic low back pain in young and middle-aged adults and may provide patients with skills for long-term management of pain. Studies have demonstrated that these approaches resulted in substantial cost savings over usual care.

ADVANCING RESEARCH ON NATURAL PRODUCTS

According to the 2012 NHIS, nearly one in five U.S. adults use botanical supplements and other non-vitamin, non-mineral dietary supplements, such as fish oil/omega-3 fatty acids and probiotics. Adverse events related to dietary supplements are estimated to contribute to 23,000 emergency department visits in the U.S. each year. To better inform consumers and their health care providers, NCCIH supports rigorous research on the biological mechanisms of the benefits and potential harmful effects of natural products with the goal of improving the body of knowledge available to health care providers and patients.

NCCIH is supporting a Center of Excellence to determine how best to study potential adverse interactions between natural products and conventional medications. The goal is to develop a definitive approach to determine the clinical relevance of supplement-drug interactions to inform design of future research and, ultimately, decision-making about using natural products and medications together.

In FY2015, NCCIH partnered with NIH's Office of Dietary Supplements (ODS) to establish the Centers for Advancing Research on Botanical and Other Natural Products (CARBON) Program. Through this program, researchers recently identified two chemicals found in grapes that could significantly reduce depression-like behaviors in mice. The systems targeted by these compounds are not the same as current pharmaceutical antidepressants and may provide novel insights into the biology of depression and could lead to new therapeutic agents. The program is also developing new methods for chemical characterization of natural product mixtures, biological profiling assays, and creating new informatic tools to rigorously analyze and share data.

NCCIH is also supporting research on cytisine, a natural product for smoking cessation. Despite promising results from clinical trials conducted outside the U.S., cytisine has not yet been approved for use in the U.S. NCCIH supported a series of pre-clinical studies on cytisine through a strategic collaboration with Achieve Life Sciences, Inc., OncoGenex Pharmaceutical, Inc., other NIH ICs, and private research organizations. Recently, the FDA accepted an Investigational New Drug application that permits phase 2 clinical studies to further assess cytisine as a smoking cessation treatment. This continuing public-private partnership may lead to the wide availability of a new option to address the major public health issues associated with tobacco use.

CONCLUSION

As a responsible steward of resources, NCCIH supports scientifically meritorious basic, mechanistic, clinical, and translational research. The Center focuses on areas with the greatest potential impact by prioritizing research topics that show scientific promise and are amenable to rigorous scientific inquiry. We leverage strategic partnerships to build the scientific evidence needed on the safety and efficacy of complementary health approaches and disseminate evidence-based information to the American public.

Helene Langevin, M.D.**Director, National Center for Complementary and Integrative Health**

Helene Langevin, M.D., was sworn in as director of the National Center for Complementary and Integrative Health (NCCIH) on November 26, 2018. Prior to her arrival, she worked at the Osher Center for Integrative Medicine, jointly based at Brigham and Women's Hospital and Harvard Medical School, Boston. Dr. Langevin served as director of the Osher Center and professor-in-residence of medicine at Harvard Medical School since 2012. She has also served as a visiting professor of neurological sciences at the University of Vermont Larner College of Medicine, Burlington.

As the principal investigator of several NIH-funded studies, Dr. Langevin's research interests have centered around the role of connective tissue in chronic musculoskeletal pain and the mechanisms of acupuncture, manual, and movement-based therapies. Her more recent work has focused on the effects of stretching on inflammation resolution mechanisms within connective tissue. She has authored more than 70 original scientific papers and is a fellow of the American College of Physicians.

Dr. Langevin received an M.D. degree from McGill University, Montreal. She completed a postdoctoral research fellowship in neurochemistry at the MRC Neurochemical Pharmacology Unit in Cambridge, England, and a residency in internal medicine and fellowship in endocrinology and metabolism at The Johns Hopkins Hospital in Baltimore.

As NCCIH director, Dr. Langevin oversees the Federal government's lead agency for scientific research on the diverse medical and health care systems, practices, and products that are not generally considered part of conventional medicine. With an annual budget of approximately \$142 million, NCCIH funds and conducts research to help answer important scientific and public health questions about natural products, mind and body practices, and pain management. The center also coordinates and collaborates with other research institutes and Federal programs on research into complementary and integrative health.

Ms. DELAURO. Thank you very, very much. I am sure we are all trying to figure out how to get more sleep here. [Laughter.]

Ms. LEE. And less stress.

Ms. DELAURO. And less stress. Thank you, Barbara.

Dr. Brennan, welcome, and thank you for being here as well. Your, again, written testimony, full written testimony is entered into the hearing record, and you are recognized for 3 minutes.

Dr. BRENNAN. Thank you, Madam Chairwoman DeLauro, Ranking Member Cole, and members of the subcommittee.

I am Patty Brennan. I am a nurse and an industrial engineer. I have spent my career developing information technology solutions to bring health information into the everyday lives of people suffering from chronic disease and illness. Now I direct the National Library of Medicine, the world's largest biomedical library and one of the 27 Institutes and Centers at the National Institutes of Health.

Every day, millions of scientists, health professionals, and the public use the NLM's electronic resources to translate research into new results, to develop new products, to inform clinical decision-making, to devise new treatments, and to improve public health. Let me show you what this actually could look like, though.

Imagine you are a parent of a child newly diagnosed with neuroblastoma, a rare childhood cancer. You have never heard of the disease before, and you want to understand it better. So what do you do?

Like millions of people every day, you turn to the NLM's MedlinePlus, which has consumer-oriented information on more than 1,000 diseases and conditions. There are 57 short articles related specifically to the diagnosis and treatment of neuroblastoma.

If there are no effective treatments approved for use, you and your physician might search the NLM's ClinicalTrials.gov database to find an appropriate study. One hundred forty-five thousand people use the Clinicaltrials.gov database every day. It contains information about more than 300,000 clinical studies ongoing and completed. Today, you would find almost 100 studies related to neuroblastoma that are actively recruiting participants across the United States.

Physicians and researchers studying neuroblastoma can use NLM's PubMed resource to keep up with the latest findings, over 30 million citations, over 40,000 of which address neuroblastoma. If they want to read a full-text article, they can go to PubMed Central and find 5.5 million full-text articles. More than 2.5 million people every day do this.

Researchers trying to discover treatments for neuroblastoma can request use of data from NLM's database of Genotypes and Phenotypes, where more than a dozen studies do relate specifically to this disease.

And finally, you and your family can use the NLM's Genetic Home Reference to get additional information about the disease and its heritable components. Not only do we maintain enormous databases of genes and journals, but we also have a vibrant intramural and extramural program that develops modern data science approaches, such as machine learning.

For example, one of our NLM-funded researchers at Stanford has an on the moment consulting service, the Green Button, that allows physicians to learn immediately about the experience of thousands of patients and find out if there are any patient like theirs, and how did that person respond.

In addition to our electronic resources, we have a human network of 7,000 public and academic health science libraries around the country, placing the NLM in every possible county in the U.S. This helps build awareness of our resources and often reaches into communities underserved.

Thank you for the opportunity to showcase the wonderful work at the National Library of Medicine. I look forward to your questions.

[The information follows:]

PREPARED STATEMENT OF PATRICIA FLATLEY BRENNAN, RN, PhD
DIRECTOR, NATIONAL LIBRARY OF MEDICINE

Madam Chairwoman and Members of the Subcommittee: I am pleased to have this opportunity to speak to you about the exciting work taking place at the National Library of Medicine of the National Institutes of Health (NIH).

ACCELERATING BIOMEDICAL DISCOVERY & DATA-POWERED HEALTH

The National Library of Medicine (NLM) plays an essential role in catalyzing basic biomedical science through its cutting-edge data science and informatics research, comprehensive information systems, and extensive research training programs. As the world's largest biomedical library, NLM acquires, organizes, and delivers up-to-date biomedical information across the United States and around the globe. NLM operates some of the most heavily used Federal websites. Millions of data scientists, health professionals, and members of the public use NLM's electronic information sources every day to translate research results into new treatments, products, and practices and provide the foundation for clinical decision making by health professionals and patients.

Leveraging its 180-year history of organizing and disseminating biomedical literature, NLM is committed to the application of emerging data science capabilities to challenges in biomedical research and public health. It does this by enhancing its data and information resources and providing leadership in both the acquisition and analysis of data for discovery. It continues to expand its core biomedical literature and genomic collections to include a broad array of health, clinical, and biological data types. It makes these data findable, accessible, interoperable, and reusable (FAIR) for research. NLM is investing in new research programs to systematically characterize and curate data describing complex health phenomena and to devise new methods to uncover the knowledge held in data. It has restructured its 16 biomedical informatics training programs to address data science as they continue to foster excellence and support a diverse workforce. NLM is in the process of developing an efficient organizational structure to accommodate emerging directions in research and services.

RESEARCH IN BIOMEDICAL INFORMATICS AND DATA SCIENCE

NLM's research programs support pioneering research and development to advance knowledge in biomedical informatics and data science. Its research portfolio spans such areas as artificial intelligence, computational biology, clinical decision support, public health surveillance, visualization, and discovery mining in digital data sets. This research encompasses areas of high importance to NIH and society at large, and for audiences ranging from clinicians and scientists to consumers and patients.

Research in data science produces novel analytical approaches and visualization tools that help scientists accelerate discovery from data and translate these findings to clinical solutions. It also aims to solve problems consumers face in accessing, storing, using, and understanding their own health data and to produce tools that make precision

medicine discoveries available and more understandable to patients. Biomedical informatics research is yielding advanced analytical methods and tools for use against large scale data generated from clinical care, leading to fuller understanding of the effects of medications and procedures as well as individual factors important in the prevention and treatment of disease processes.

Recognized as a leader in clinical information analytics, NLM supports and conducts research in areas such as medical language processing, high-speed access to biomedical information, analysis and use of high quality imaging data, health data standards; and analysis of large databases of clinical and administrative data to predict patient outcomes and validate findings from clinical research studies. Leveraging extensive machine learning experience and field-based projects, NLM is now advancing analytical tools and deep learning techniques for application in image analysis research.

NLM's biomedical informatics research also addresses issues in computational biology. Research creates new ways to represent and link together genomic and biological data and biomedical literature and produces analytic software tools for gaining insights in areas such as genetic mutational patterns and factors in disease, molecular binding, and protein structure and function.

Last year, NLM established a new partnership with the National Science Foundation to support research on advanced analytical methods specifically applied to health.

BIOMEDICAL INFORMATION SYSTEMS FOR RESEARCH AND HEALTH

NLM develops and operates a set of richly linked databases that promote scientific breakthroughs and play an essential role in all phases of research and innovation. Every day, NLM receives up to 15 terabytes of new data and information, enhances their quality and consistency, and integrates them with other NLM information. It responds to millions of inquiries per day from individuals and computer systems, serving up some 115 terabytes of information. This includes genomic data, such as that contained in the Sequence Read Archive, as well as citations to more than 30 million journal article records in PubMed.

On any given day, more than 2.5 million people use NLM's PubMed Central (PMC) to retrieve more than 5 million full-text biomedical journal articles. PMC serves as the repository for NIH's Public Access Policy and includes more than one million articles summarizing the results of NIH-funded research. Additionally, ten other federal agencies use PMC as the repository for publications collected under their public access policies.

Recently, NLM enhanced the ability to connect articles in PMC to openly available datasets that support reported research findings. Currently, more than 300,000 articles in PMC include datasets as supplemental materials. Others link to datasets

hosted in other trusted repositories. The addition of this information has resulted in a 30 percent increase in daily downloads of supplementary material from PMC.

NLM also offers sophisticated retrieval methods and analysis tools to mine this wealth of data, many of which grow out NLM's research and development programs. For example, NLM tools are used to mine journal articles and electronic health records (EHRs) to discover adverse drug reactions, analyze high throughput genomic data to identify promising drug targets, and detect transplant rejection earlier so interventions to help clinical research participants can begin more quickly. Data analysis tools also support complex analyses of richly annotated genomics data resources, yielding important molecular biology discoveries and health advances for applications to clinical care. Such applications demonstrate how the benefits of big data critically depend upon the existence of algorithms that can transform such data into information.

As a major force in health data standards for more than 30 years, NLM's investments have led to major advances in the ways high volume research and clinical data are collected, structured, standardized, mined, and delivered. In close collaboration with other HHS agencies, NLM develops, funds, and disseminates clinical terminologies designated as essential for demonstrating meaningful use of EHRs and health information exchange. The goal is to ensure that clinical data created in one system can be transmitted, interpreted, and aggregated appropriately in other systems to support health care, public health, and research. NLM produces a range of tools to help EHR developers and users implement these standards and makes them available in multiple formats, including via application programming interfaces or APIs. NLM is now providing support to develop tools to facilitate research use of the Fast Healthcare Interoperability Resource, or FHIR, standard that is being widely adopted for use in electronic health records.

ENGAGING THE PUBLIC WITH HEALTH INFORMATION

NLM uses multiple channels to reach the public with health information, including development of consumer-friendly websites, direct contact, and human networks that reach out to communities. Direct-to-consumer information is made available in lay language through MedlinePlus, which covers more than 1000 health topics. EHR systems can connect directly with MedlinePlus to deliver information to patients and health care providers at the point of need in healthcare systems. In collaboration with other NIH Institutes and Centers and other partners, NLM produces the print and online *NIH MedlinePlus* magazine, and its Spanish counterpart, *NIH Salud*.

The National Network of Libraries of Medicine (NNLM) engages more than 7,000 academic health sciences libraries, hospital libraries, public libraries, and community-based organizations as valued partners in conducting outreach to ensure the availability of health information and efficient access to NLM services. The NNLM provides a community-level resource for NIH's *All of Us* program, ensuring a point of presence in almost every county in the US. The NNLM provides a robust network that reaches communities that are often underrepresented in biomedical research.

NNLM partners with local, state, and national disaster preparedness and response efforts to promote more effective use of libraries and librarians and ensure access to health information in disasters and emergencies. NNLM also plays an important role in increasing the capacity of research libraries and librarians to support data science and improve institutional capacity in management and analysis of biomedical data.

CONCLUSION

To conclude, through its research, information systems and public engagement, NLM supports discovery and the clinical application of knowledge to improve health. Its programs provide important foundations for the field of biomedical informatics and data science, bringing the methods and concepts of computational, informational, quantitative, social, behavioral, and engineering sciences to bear on problems related to basic biomedical and behavioral research, health care, public health, and consumer use of health-related information.

Patricia Flatley Brennan, RN, PhD
Director, National Library of Medicine

Patricia Flatley Brennan, RN, PhD, is the Director of the National Library of Medicine (NLM) at the National Institutes of Health (NIH). NLM is the world's largest biomedical library and producer of digital information resources used by scientists, health professionals, and members of the public. Since becoming director in August 2016, Dr. Brennan has positioned the Library to be the epicenter for biomedical data science at NIH and across the biomedical research enterprise globally. Her leadership has led to the development of a new strategic plan that refocuses and enhances NLM's research, development, training, and information systems. By leveraging NLM's heavily used data and information resources and programs, Dr. Brennan is strengthening and advancing NLM's data infrastructure to accelerate data-driven discovery and health, engage new users in new ways, and develop the workforce for a data-driven future.

Prior to joining NIH, Dr. Brennan was the Lillian L. Moehlman Bascom Professor in the School of Nursing and College of Engineering at the University of Wisconsin–Madison. She also led the Living Environments Laboratory (now the Virtual Environments Group) at the Wisconsin Institute for Discovery, which develops new methods for the effective visualization of high-dimensional data.

Dr. Brennan is a pioneer in the development of innovative information systems and services, and her professional accomplishments reflect her background, which unites engineering, information technology, and clinical care to improve public health and ensure the best possible experience in patient care.

Dr. Brennan received a Master of Science in Nursing from the University of Pennsylvania and a PhD in industrial engineering from the University of Wisconsin–Madison. Following seven years of clinical practice in critical care nursing and psychiatric nursing, she held academic positions at Marquette University, Case Western Reserve University, and the University of Wisconsin–Madison.

A past president of the American Medical Informatics Association, Dr. Brennan was elected to the National Academy of Medicine in 2001. She is a fellow of the American Academy of Nursing, the American College of Medical Informatics, and the New York Academy of Medicine.

Ms. DELAURO. Thank you very, very much. Dr. Pérez-Stable, your full written testimony will be entered into the record, and you are recognized for 3 minutes.

Dr. PEREZ-STABLE. Thank you, and good morning.

I would like to thank Chairwoman DeLauro, Ranking Member Cole, and esteemed members of the subcommittee. It is really an honor to be here today.

My name is Dr. Eliseo Pérez-Stable. I am the Director of the National Institute on Minority Health and Health Disparities. I arrived at NIMHD 4 years ago after 32 years at the University of California at San Francisco, where I was a practicing general internist, educator, and clinician scientist.

I became a researcher because of my passion for understanding the factors that affect minority health and to address health equity. As a practicing primary care physician, I learned to appreciate the power of therapeutic relationships. I witnessed health disparities in our minority communities at every level of healthcare and noted the lack of diversity among my peers. I came to NIMHD because of the opportunity to help shape the field of minority health and health disparities research at a national level.

NIMHD is moving beyond simply identifying the health disparities that exist to understanding mechanisms and developing the interventions to reduce these disparities. We take into account behavior and biology; the individual and structural social determinants of health; the built environment where we live, learn, work, and play; how people interact in our communities; and healthcare.

Through developments such as geographic information systems, we can now understand the personal factors and social interactions that contribute to disparities in defined neighborhoods. For example, we know that life expectancy of individuals may vary by 20 years from one neighborhood to another within the same city, but full explanations are still lacking.

Place matters in health. Or as many have said, your zip code is more important than your genetic code in determining your health.

Asthma is the most common chronic disease of children in America and disproportionately affects African Americans and Puerto Ricans. Ongoing research in asthma has shown that children from different ethnic and racial backgrounds do not respond to medication treatment for asthma in the same way. There are genes that protect and genes that increase risk for asthma among these populations, with environmental and geographic factors that influence exacerbations of disease.

Lastly, we know diverse groups are more effective and innovative in science and other fields. NIMHD's Center programs are designed to build institutional research capacity, create opportunity for diverse early-stage investigators to succeed, and cultivate strong community engagement as part of the research process.

We believe this is a sustainable intervention that will help address the lack of diversity in the scientific biomedical workforce. Through this scientific research agenda, I am optimistic that NIMHD's funded scientists will lead to discoveries that will promote health equity.

My patients from all backgrounds trusted that I would strive to recommend the best possible clinical care for them, regardless of the diagnosis. Ultimately, NIMHD envisions an America in which all populations will have an equal opportunity to live long, healthy, and productive lives.

Thank you, and I look forward to your questions.

[The information follows:]

PREPARED STATEMENT OF ELISEO J. PÉREZ-STABLE, M.D.

DIRECTOR, NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH
DISPARITIES

Good Morning, Madam Chairwoman and Members of the Subcommittee, I am Eliseo Perez-Stable, M.D., Director of the National Institute on Minority Health and Health Minorities of the National Institutes of Health (NIH).

ADVANCING THE SCIENCE OF MINORITY HEALTH AND HEALTH DISPARITIES RESEARCH

Today, revolutionary advances in biomedical science, such as the emergence of genomics, precision medicine, and health information technology hold greater promise to improve our nation's health than has ever before been possible. We are on the cusp of major scientific advances that will change how we think about minority health and health disparities. The mission of the National Institute on Minority Health and Health Disparities (NIMHD) is to lead scientific research to improve minority health and reduce health disparities. To accomplish this, NIMHD plans, coordinates, reviews, and evaluates NIH minority health and health disparities research and activities; conducts and supports research in minority health and health disparities; promotes and supports the training of a diverse research workforce; translates and disseminates research information; and fosters innovative collaborations and partnerships. As part of its charge to improve minority health and reduce health disparities, NIMHD is currently developing the *2020-2024 NIH Minority Health and Health Disparities Strategic Plan*. Plan in collaboration with the NIH Institutes and Centers and input from community partners and key stakeholders. Once completed, this strategic plan will provide a blueprint to advance the direction and goals of minority health and health disparities research.

As the science of minority health and health disparities research evolves, a critical multidisciplinary approach is needed to focus on research studies that facilitate scientific advances to improve minority health and to reduce health disparities. Minority health research is the scientific investigation of distinctive health characteristics and attributes of minority racial and/or ethnic groups who are underrepresented in biomedical research in order to understand population health outcomes. Health disparities research is a field of study devoted to gaining greater scientific knowledge about the influence of health determinants, understanding the role of different pathways leading to disparities, and determining how findings translates into interventions to reduce health disparities. In order to ensure that all populations have an equal opportunity to live healthy and productive lives, NIMHD leads advancement in minority health and health disparities research and promotes a diverse scientific workforce reflective of the population.

RESEARCH

Advancing the science of minority health and health disparities requires scientific vision; that means building and developing evidence-based information that takes into account the social determinants of health and the places where we live, learn, work, and play. To meet the demands of keeping up with biomedical advances, NIMHD is redefining, reorganizing, and establishing new research programs and activities. This enables NIMHD to strengthen research in minority health and health disparities; increase opportunities for investigator-initiated research; strengthen the evaluation and reporting of minority health and health disparities research; and support the expansion of workforce diversity.

NIMHD's transformative scientific agenda promoted the fields of minority health and health disparities by developing and posting NIMHD's Research Framework, which addresses the complex influences on health and health disparities. Specifically, the Research Framework reflects an evolving conceptualization of factors relevant to the understanding and promotion of minority health and to the understanding and reduction of health disparities. The framework focuses on how these influences affect individuals, families, communities and society at large. It serves as a vehicle for encouraging NIMHD- and NIH-supported research that addresses the complex and multi-faceted nature of minority health and health disparities and guides researchers on where on the scientific spectrum their research fits.

NIMHD's increased emphasis on the science of minority health and health disparities has evolved into the three focused areas of clinical and health services research, integrative biological and behavioral research and community health and population sciences. The Clinical and Health Services Research area generates new knowledge to improve health outcomes and quality of health care for minority and underserved populations within the context of everyday clinical practice. It examines the development of preventive, diagnostic and therapeutic healthcare interventions that can contribute to reducing health disparities and how precision patient-clinician communication may reduce health disparities. Moreover, it supports clinical research that generates new knowledge to improve health outcomes and quality of healthcare. For example, researchers found that childhood cancer survivors who reported greater well-being, rated religion and spirituality of high importance, accessed specialized cancer services more regularly, and expressed a greater level of health care self-efficacy.

The Integrative Biological and Behavioral Research area examines research on how biological and behavioral mechanisms and pathways influence resilience and susceptibility to adverse health conditions that disproportionately affect racial and ethnic minority populations, persons of less privileged socioeconomic status, and other health disparity populations. Research examples in this area include, genomic and epigenomic

risk and protective factors; human microbiome contributions to health and disease; and mechanisms through which behavioral risk and protective factors influence the development of adverse health conditions by triggering adverse biological pathways. For example, research found that DNA methylation can be used to accurately estimate gestational age and may be a useful tool in addressing persistent higher rates of low birth weights for some minority populations.

The Community Health and Population Sciences research area focuses on community engaged research and large studies of populations in a defined geographic area that reflect overall health of minority and underserved population groups. Community engagement refers to the active participation of community members in contributing to the research process in a partnership with investigators. Studies within this area examine causes, prevention, screening, early detection, and management of disease such as epidemiologic studies that identify and describe disease burden and risk factors in disparity populations; behavioral, sociocultural, and environmental influences on disease risks and outcomes; and research integrating the multiple determinants of health at the biologic, behavioral, and contextual levels and their interactions. In a study examining the perspective of older breast cancer survivors toward physical activity, researchers found that physical activity programs should focus on cancer treatment related concerns and include strength training.

Innovative partnerships and collaborations are instrumental and essential to improve minority health and reduce health disparities. NIMHD supports research partnerships across NIH and the federal government with a goal to create synergistic research approaches to improve public health for health disparity populations. Partnerships conducted and supported by the NIMHD have created innovative studies into how to promote screening for breast, prostate, and pancreatic cancers; examine how children's experiences affect brain development; investigate the effects of environmental exposures — including physical, chemical, biological, social, behavioral, natural and built environments — on child health and development; understand the sources of persistent health disparities in overall longevity, cardiovascular disease, and cerebrovascular disease; and to eventually eliminate health disparities in dental care and oral/pharyngeal cancer.

BUILDING A DIVERSE BIOMEDICAL WORKFORCE

At the core of NIMHD's transformative scientific agenda is its commitment to building institutional research capacity and a diverse cadre of minority health and health

disparities researchers. The Centers of Excellence program creates collaborative hubs for minority health and health disparities research among research institutions and local communities, which support early-career scientists as well as established investigators. The Research Centers in Minority Institutions program builds research capacity, supports a new generation of researchers from underrepresented populations through pilot funding, and established scientists conduct cutting edge science in basic, behavioral or clinical research topics. The Research Endowment program provides funds to low resource academic institutions with a diverse student body and faculty, to support endowments that will help to support a training or research capacity program to promote minority health and health disparities research.

NIMHD is committed to supporting and developing a diverse biomedical workforce. We support training grants across the spectrum of experience from pre-doctoral awards through mid-career awards. Moreover, NIMHD has enhanced opportunities for early-stage investigators by: expanding awards to help senior postdoctoral fellows and junior faculty-level candidates to become competitive for major grant support; providing fellowships to help less experienced researchers to become productive, independent investigators and; restructuring the NIMHD Health Disparities Research Institute to support the career development for promising early-career minority health and health disparities research scientists.

CONCLUSION

NIMHD continues to advance the science of minority health and health disparities by building upon evidence-based research; developing researchers from underrepresented populations and retaining their diverse insights; and enhancing programs that create research infrastructure and train a diverse scientific workforce. Through this scientific research agenda, NIMHD's mission and vision will lead to discoveries that will promote health equity and ultimately improve minority health and reduce health disparities.

Eliseo J. Pérez-Stable, M.D.

Director, National Institute on Minority Health and Health Disparities

Eliseo J. Pérez-Stable, M.D. is Director of the National Institutes of Health's National Institute on Minority Health and Health Disparities (NIMHD), which seeks to advance the science of minority health and health disparities research. NIMHD is the newest institute at NIH and had a budget over \$314 million in 2019. NIMHD also promotes diversity in the biomedical workforce. Under this framework, the Institute conducts and supports research programs to advance knowledge and understanding of mechanisms to improve minority health, identifies and understands health disparities and develops effective interventions to reduce these disparities in community and clinical settings. NIMHD is the lead organization at the National Institutes of Health (NIH) for planning, reviewing, coordinating, and evaluating minority health and health disparities research activities conducted by NIH.

Prior to becoming NIMHD Director in September 2015, Dr. Pérez-Stable practiced general internal medicine for 37 years at the University of California, San Francisco (UCSF) before moving to NIH in September 2015. He was professor of medicine at UCSF and chief of the Division of General Internal Medicine for 17 years.

Dr. Pérez-Stable's research expertise spans a broad range of minority health and health disparities disciplines. His research interests include improving the health of racial and ethnic minorities and underserved populations, advancing patient-centered care, improving cross-cultural communication, and promoting diversity in the biomedical research workforce. For more than 30 years, Dr. Pérez-Stable led research on Latino smoking cessation and prevention interventions in the U.S. and Jujuy, Argentina, epidemiology of tobacco behavior among minority populations, tobacco biomarkers in subpopulations, cancer control behaviors, use of interpreters in medical care, and clinical, social and behavioral issues in minority aging. He has mentored over 70 minority investigators, published over 280 peer-reviewed articles and was elected to the National Academy of Medicine in 2001.

Dr. Pérez-Stable is a native of La Habana, Cuba and immigrated to the U.S. as a child. He earned his B.A. in chemistry in 1974 and M.D. in 1978 from the University of Miami, and completed clinical training in primary care internal medicine residency and general internal medicine research fellowship at UCSF. Dr. Pérez-Stable practiced primary care internal medicine for 37 years at UCSF following a panel of about 200 patients at any given time. He also supervised and taught students and residents in the continuity ambulatory care clinic and on the medical service in the hospital setting.

Ms. DELAURO. Thank you very much.

Dr. Austin, your full written testimony will be entered into the record, and you are recognized for 3 minutes. Many thanks for being here.

Dr. AUSTIN. Thank you, and good morning, Chairwoman DeLauro, Ranking Member Cole, and distinguished subcommittee members. My name is Christopher Austin. I am a clinical neurologist and a basic science geneticist by training, and I have spent my career trying to bridge that gap, which we now call translation in both the academic and the pharmaceutical industries.

And I am now proud to be Director of the National Center for Advancing Translational Sciences, or NCATS. NCATS was established almost 8 years ago now to address a central biomedical issue of our time, which is how to dramatically accelerate translation, which is the process of turning observations made in the laboratory, the clinic, or in the community into interventions that improve the health of individuals in the public.

NCATS is focused on the science of translation, understanding of which will allow us to overcome common roadblocks to success and increase efficiency of the translational research process for all. In short, NCATS mission is, to paraphrase Matt Damon's character in the movie "The Martian," is to "science the heck" out of translation.

A few examples to illustrate our approach and successes so far. First, to look for commonalities. Rather than focus on what is different among diseases, NCATS focuses on what is common to diseases and common to the translational process, allowing us to transition from a one disease at a time to a many diseases at a time therapeutic approach.

For example, our Platform Gene Therapy Program is developing standard gene therapy vehicles, or vectors, for unrestricted use in potentially hundreds or even thousands of different diseases.

Second, NCATS Cures Acceleration Network, or CAN, CAN supports initiatives that advance the development of high-need cures. The CAN Tissue Chip Program is addressing the frequent cause of translational failure due to animal models not accurately predicting safety or effectiveness of new drugs in people. Tissue chips are made of human cells and can better model human organs, diseases, and response to candidate drugs.

As an example, tissue chips of the human kidney, and I happen to have a kidney with me here today, have been developed to study polycystic kidney disease, a condition not well replicated in animal models.

And finally, collaboration is a team sport. This is one of NCATS' operational mantras, and we find that the more diverse our teams are, the bigger the problems are we are able to solve. So every project NCATS does is a collaboration with another Institute or Center or an outside partner.

For example, the CTSA Trial Innovation Network, or TIN, includes a Recruitment Innovation Center that has developed innovative approaches to collaborating with diverse patient communities in the planning and implementation of clinical studies. These community engagement studios have recently helped researchers better design studies to determine the health effects of exercise in children with sickle cell disease and cystic fibrosis.

Involvement of patients and communities in the research we hope will benefit them is another central NCATS strategy for increasing translational efficiency.

So when I became NCATS' first permanent Director 7 years ago this week, it was unclear whether our ambitious mission to close the translational gap could actually be achieved. Our accomplishments since then make me more optimistic than I have ever been that we can, indeed, both understand translation as a science and use that knowledge to dramatically increase the efficiency of the process of developing treatments and cures and, in so doing, help bring the promise of science to patients in need.

I thank the committee for its support and confidence in our mission and would be happy to answer any questions.

[The information follows:]

PREPARED STATEMENT OF CHRISTOPHER P. AUSTIN, M.D.
DIRECTOR,
NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

The National Center for Advancing Translational Sciences (NCATS) is dedicated to understanding and transforming **translation**, defined as the process of turning scientific, medical, and public health observations in the laboratory, clinic, and community into interventions that improve the health of individuals and the public. At a time of unprecedented fundamental science discoveries, our collective ability to translate research findings into health benefits often is too slow and ineffective. Developing a new drug requires on average 10 to 15 years and more than \$2 billion given the high prevalence of failure along the translational pipeline. We must deliver the promise of science to patients and the public in an accelerated and more efficient manner. NCATS studies and supports translation on a system-wide level as a scientific and operational problem, addressing roadblocks that impede or preclude promising research advances.

Hastening Clinical Translation

The largest portion of NCATS' budget is dedicated to its Clinical and Translational Science Awards (CTSA) Program, which supports a national network of medical research centers, called hubs. The hubs collaborate locally, regionally, and nationally to foster innovation in clinical researcher training, patient involvement, and new research tools and processes. There are multiple initiatives within this program, including the Trial Innovation Network that is composed of Trial Innovation Centers, a Recruitment Innovation Center, and the CTSA Program hubs. Through this network, researchers are identifying and implementing ways to improve the clinical trial process, including participant recruitment and other aspects of clinical trial conduct.

The process of obtaining ethics approval for multisite clinical research by multiple institutional review boards (IRBs) is a longstanding challenge that can lead to significant delays in study activation. To address this problem, NCATS supported the development of a single IRB reliance platform for multisite clinical studies, enabling study sites to rely on a single IRB of record. The platform, known as the Streamlined, Multisite, Accelerated Resources for Trials (SMART) IRB, includes resources such as umbrella agreements, guidance documents, and technical assistance that institutions nationwide can access to streamline IRB review for multisite studies. SMART IRB is serving as a roadmap to help implement the NIH policy released in June 2016 that generally expects all sites participating in multi-site studies, which involve non-exempt human subjects research funded by the NIH to use a single IRB to conduct the ethical review required for the protection of human subjects.

Providing the resources to train, cultivate, and sustain future leaders of the biomedical research workforce is another key CTSA Program goal. The program supports a coordinated, national effort to help ensure a pipeline of trained translational

investigators who can move basic research findings into applications for improving health as novel therapies, diagnostics, and preventives. Program grantees have developed clinical and translational sciences training resources, including educational core competencies, best practices for training mentors, and curriculum materials. These tools are freely available and many institutions nationwide are using them.

Engaging patients at all stages of translation is crucial: Their perspectives as members of the research team provide insights, focus, urgency and connectivity that can be instrumental in making the development, testing and deployment of new interventions more effective. NCATS supports the Rare Diseases Clinical Research Network (RDCRN) which emphasizes including patient groups as full partners on the consortium research teams, an approach that helps achieve greater success. The RDCRN Coalition of Patient Advocacy Groups develops and shares best practices, and the RDCRN website includes a contact registry for patients who may be interested in participating in RDCRN clinical studies. Rare diseases, which cumulatively affect approximately one in 10 people in the U.S., are in crucial need of innovative translational technologies, so are a particular focus for NCATS.

Measurable outcomes can help determine whether a new translational process is actually an improvement. NCATS' Discovering New Therapeutic Uses for Existing Molecules program matches academic investigators with pharmaceutical companies that have compounds that were found to be ineffective in treating specific targeted diseases. Repurposing these compounds for potentially treating other diseases saves time in the drug development process because significant foundational work already has been completed. NCATS helps to further accelerate this process by providing collaboration agreement templates that now are being used broadly in the research community and by supporting researchers with new ideas for how existing compounds can be repurposed.

Finding New Therapies for Clinical Study

NCATS also is dedicated to removing pre-clinical translational science roadblocks. Through its Therapeutics for Rare and Neglected Diseases (TRND) program, the Center works to “de-risk” potential therapeutics so that private sector companies can feel more confident about acquiring them to finish their development.

Through its Tissue Chip for Drug Screening program, NCATS is working on new methods for predicting both safety and efficacy of experimental drugs using engineered “chips” that contain human cells and model human organs. Current methods such as animal and cell models are not always reliably predictive and can result in wasted time and effort. In addition to developing these chips for testing potential drugs, NCATS sent tissue chips to the International Space Station (ISS) to conduct research on the effect of microgravity on these model organs. Microgravity has been observed to accelerate aging and have other effects relevant to diseases on earth, making the ISS a unique yet significant research environment.

New drug development for currently untreatable diseases has been greatly limited because known chemical structures affect only 10 percent of potential drug targets within the human body. To help move past this impediment, NCATS launched its Automated Synthesis Platform for Innovative Research and Execution (ASPIRE) program to bring together chemistry, robotic engineering, biological activity testing, and artificial intelligence. Tools developed through ASPIRE will minimize the amount of time chemists spend on tedious and repetitive tasks, freeing them up for more complicated pursuits such as designing, synthesizing, and testing compounds for diseases that currently have no FDA-approved treatment.

Adaptability to Tackle Emerging Public Health Needs

With its unique collection of programs, initiatives and resources, NCATS has the capacity and capability to address public health crises. For example, a team of researchers from NCATS and the Icahn School of Medicine at Mount Sinai developed a miniaturized assay for high-throughput screening to find compounds that block the ability of Ebola virus-like particles (VLPs) to enter and infect cells. A screen using 2,816 compounds identified 53 drugs with entry-blocking activity against Ebola VLPs.

In another example, investigators from Johns Hopkins University and Florida State University collaborated with NCATS experts on drug repurposing and high throughput screening to identify rapidly two classes of existing compounds that potentially can be used to fight Zika. These compounds were effective either in inhibiting the replication of Zika virus or in preventing the virus from killing brain cells. All data has been made available to public databases, allowing these compounds to be further studied by the broader research community to help combat the Zika health crisis.

NCATS also is combatting the current national epidemic of opioid abuse. Approaches can include using the Center's high-throughput screening facility to test potential opioid abuse therapeutics and requiring CTSA Program-supported researchers to help identify opioid patients and rapidly enroll them in newly initiated multisite clinical trials.

Conclusion

Through its programs and initiatives described above, and others, NCATS is improving health through smarter science in unprecedented ways, with the ultimate goal of getting more treatments to more patients — and to the public at large — more quickly.

Christopher P. Austin, M.D.
Director, National Center for Advancing Translational Sciences

Dr. Austin leads NCATS' work to improve the translation of observations in the laboratory, clinic and community into interventions that reach and benefit patients—from diagnostics and therapeutics to medical procedures and behavioral changes. Under his direction, NCATS researchers and collaborators are developing new technologies, resources and collaborative research models; demonstrating their usefulness; and disseminating the data, analysis and methodologies for use by the worldwide research community.

Austin's career has spanned the spectrum of translational research, in the public and private sectors. Austin joined NIH in 2002 as the senior advisor to the director for translational research at the National Human Genome Research Institute, where he was responsible for conceptualizing and implementing research programs to derive scientific insights and therapeutic benefit from the newly completed Human Genome Project. While at NHGRI, he founded and directed the NIH Chemical Genomics Center, Therapeutics for Rare and Neglected Diseases program, Toxicology in the 21st Century initiative, and NIH Center for Translational Therapeutics. Upon creation of NCATS in 2011, he became the inaugural director of the NCATS Division of Pre-Clinical Innovation, and was appointed NCATS director in 2012. In 2016, Dr. Austin was elected chair of the International Rare Disease Research Consortium (IRDiRC). Prior to joining NIH, Austin worked at the pharmaceutical company Merck, where he directed programs on genome-based discovery of novel targets and drugs, with a particular focus on schizophrenia and Alzheimer's disease.

Austin is trained as a clinician and geneticist. He trained in internal medicine and neurology at the Massachusetts General Hospital in Boston, and practiced medicine in academic and community hospital settings as well as in urban primary care and in rural Alaska and Africa. He completed a research fellowship in developmental neurogenetics at Harvard, studying genetic and environmental influences on stem cell fate determination. Austin earned an M.D. from Harvard Medical School and A.B. summa cum laude in biology from Princeton University.

Ms. DELAURO. Thank you all very, very much.

I have a question that goes to the panel. Much of the success of biomedical research in the U.S. is attributed to NIH's strong support of basic research ideas and proposals, individual scientists at the NIH, across the country, and many of the ideas led to major discoveries came from the bottom up and not from the top down.

At the same time, as the Director of the Institutes and experts in your fields, you have a unique vantage point to target resource to specific areas of research that might be especially promising or compelling or that may have been neglected or short-changed.

The question is how do you strike that balance in allocating resources between investigator-initiated research and targeted initiatives? So whoever would like to start. We don't have to go in order, but whoever would like to start to answer the questions.

I am going to ask each of you that question. How do you strike that balance?

Dr. TROMBERG. So thanks for your question. It is actually a very easy one for us in some sense. We are constantly communicating, interacting with our community. We have many methods of convening the community together with conferences and workshops, and we are quite responsive to state-of-the-art and needs from the community.

As a result of many of those discussions and conferences and working together with our colleagues, we are able to create targeted opportunities that will respond to those needs. So there is a kind of a push and a pull that is very dynamic. It is ongoing. It is very fluid, and we have a number of mechanisms for both accelerating targeted mechanisms, as well as encouraging the individual investigator applications.

Ms. DELAURO. Go ahead, Doctor. Yes, Dr. Brennan.

Dr. BRENNAN. At the NLM, we sometimes release notices of areas of interest. So right now, we have vast databases, and we know that some of these databases may have sparse, incomplete datasets that may be biased in some way.

So we have released a notice to the community saying we want to understand mathematical approaches to making sure the databases are better. We let the community decide how to respond.

Ms. DELAURO. I will be quick about it. You both talked about community. Identify the community.

Dr. BRENNAN. Oh, good, that is—thank you very much.

Ms. DELAURO. And you, too, Doctor Tromberg—

Dr. BRENNAN. In our case, it is the data science and medical informatics community. And beyond them, the clinical care community.

Ms. DELAURO. OK. Dr. Tromberg, just quickly.

Dr. TROMBERG. In our case, it is the biomedical engineering and bioimaging community, which are often distributed in radiological science departments, radiology, and bioengineering in the country.

Ms. DELAURO. Thank you.

Dr. PÉREZ-STABLE. So when I arrived at NIMHD, most of the portfolio was already targeted. So I shifted some of those funds to create a new pool of investigator-initiated applications. And we are about 50–50 now, and I think—we will have to see how it goes over the next several years.

So we have Center program, we have loan repayment, we have endowment program, we have targeted programs. Now the—our community, which are the minority health/ health disparity scientists spread across academic health centers, schools of public health, some organizations, non-academic affiliated organizations, are responding to ideas that we have put out, but also on their own ideas.

Ms. DELAURO. Mm-hmm.

Dr. AUSTIN. And I would note and answer it this way. I think the way we think about this, that distribution depends on the kind of science that you are trying to do. In basic science, the investigator-initiated model works really well because the individual person is the unit of productivity.

I mentioned that translation is a team sport. It doesn't matter how smart you are or how devoted you are, you can't do it by yourself. You need a community of about 20 different disciplines in order to do that.

So the way we tend to think about our programs, the way we structure all of them is that we have programs, like the CTSA program, which support individual programs, and those programs that those individual projects happen within this ecosystem which allows them to succeed. However, I must say one of the things that NCATS is really working on is to have an investigator-initiated pool, which we currently do not have, and I think is really, really necessary for the translational science community academically to flourish.

Ms. DELAURO. Thank you. Dr. Langevin, yes?

Dr. LANGEVIN. Well, at NCCIH, we study treatments and practices that are already occurring in the patient community. This is a grassroots kind of phenomenon that is going on. So it is a natural thing for us to want to extend our research into what we call the real world. Now how are these treatments actually being implemented? How is it possible to bring something like, for example, acupuncture into a hospital and have it be basically integrated with the rest of the care that is going on?

So we have a sort of a translational arc that goes all the way into implementation, and those types of grants are large-scale projects that we perform in collaboration between NCCIH and the outside investigators.

On the other hand, we have some investigator-initiated basic research to understand the mechanisms. How do these things work? How does something like acupuncture work? And so we do basic research all the way down to animal models, and mostly we rely on the creativity of the community to go there.

Dr. COLLINS. Just one sentence, if I might? This is a very important question, Madam Chairwoman, and something that we obviously think about a lot at NIH. I would point you to the NIH Strategic Plan, which we put together about 3 years ago and which is now getting ready for a refresh because it is supposed to be done every 5 years. And it has a whole section on sort of how do we balance investigator-initiated efforts, sort of the bottom-up part of what we do, with identifying areas that need a push, the top-down part, and how do we get that balance right?

And as you heard, it is different for every Institute, and it should be.

Ms. DELAURO. Congressman Cole.

Mr. COLE. Thank you very much, Madam Chair.

I am going to direct my first two questions to Dr. Collins because I want to, frankly, get these on the record. As the chair accurately pointed out, we have had 4 years of bipartisan sustained growth here. I know that is her plan. Certainly, it is in the bill that she has prepared for fiscal year 2020.

So, Dr. Collins, if you could quickly tell us what sort of difference has that made in the last 4 or 5 years? I don't mean the specific things, but just in terms of the environment for biomedical research. And then what are the advantages if the Congress chooses to continue on that course?

Dr. COLLINS. Well, I really appreciate the question, and it has been such a shot in the arm to our whole community—and here, I am talking about the research community across many different disciplines and different institutions—to have had this upward trajectory that you, the appropriators, have managed to sustain now for 4 years, going on 5. And that has changed the whole morale of the community in very substantial ways.

I have got to tell you, when I would go and visit a university in 2014, it was sometimes difficult to meet with the trainees because they were anxious about whether there was a future for them and whether they got into the wrong field. I don't hear that anymore. I hear a lot of excitement and a lot of energy.

Over these last 4 years, my gosh, the things that have happened, a lot of them in the area of technology. You mentioned what you saw when you went and visited in Oklahoma, where they are making basically in a petri dish something that they can study in infectious disease, RSV. That is happening in lots of different laboratories with the ability to do this kind of regenerative medicine research.

The single-cell biology revolution, which, 5 years ago, we really didn't know how to study biology in a single cell. Now we do, and that has just completely transformed our understanding of human biology but also given us insights into treatments.

In terms of the therapeutics, the revolution in gene editing has been accelerated by the opportunity to take risks here with something called CRISPR. And I don't know how many of you got to see the 60 Minutes piece about 6 months ago. An individual at our Clinical Center who appears now to be cured of sickle cell disease because of the opportunity to take gene therapy to a whole other level that we didn't think we would be able to do this soon.

All of that takes a lot of money and resources. It means taking risks where you don't know if it is going to work or not. And you have given us that kind of confidence that we can make those investments with this particular pathway.

The one I would say is most important, though, is actually investing in the next generation of researchers. I was really worried about that 5 or 6 years ago. Again, it was very hard for a new faculty member to be sure that they were going to be able to get NIH support, and that is kind of the requirement if you are going to be able to run a research lab at an institution around this country in

an academic environment. We funded about 600 of those first-time investigators in 2013. Last year, we set a very high mark, and I challenged all the Institutes to hit it, of 1,100. We funded 1,287.

This year, as of this morning, we also set an 1,100 goal. We have exactly 1,287 again. And we are not done with the year yet. So we are going to break through that. That will be a new record. But we could not do that if it were not for the improved circumstances that you have made possible.

And going forward, again, all of those same things apply, the ability to ramp the technology up, to support programs like All of Us that is enrolling a million Americans in the largest-ever long-term prospective study of health and illness, which is going to be critical.

The big data and artificial intelligence opportunities, which I see maybe as one of the most exciting and significant developments and where we have a working group that is going to give me a whole lot of recommendations in December about how we should be doing more in that space. All of that becomes more possible with what we see as potentially a good outcome for fiscal year 2020.

So I can't thank you enough.

Mr. COLE. Well, you just did. But I think you highlighted the importance of us continuing on the path that we have embarked on.

I have a quick question in the time I have got left that I think you are going to want to answer, too, and that is the National Academies of Science and Engineering and Medicine released a report last month highlighting the challenges your agencies face to maintain the Bethesda campus. The campus contains more than 12 million square feet of facilities, nearly 100 buildings.

Due to insufficient funding for buildings and facilities and other infrastructure needs, essential maintenance for many facilities and the campus overall has been deferred for many years. So I want to thank you for bringing this to our attention and doing such a thorough review.

I think this is actually something that we ought to, Chairman, interject into our discussions when the Senate follows your lead and actually gets a bill done because I think this is something we need to really focus on, and I would like you just to comment on the adequacy of your infrastructure.

Dr. COLLINS. Well, I really appreciate that question. It is a critical issue. As the National Academy report documented, we are about \$1,300,000,000 behind where we need to be in order to support the infrastructure of the NIH campus, and that is mostly the Clinical Center, the largest research hospital in the world.

They recommended an investment of \$700,000,000 over a 5-year period just to catch up with all the deferred maintenance, which has led to all kinds of problems that we have recently experienced in terms of major leaks and so on. But they also said we need another \$600,000,000 for really new investments into badly needed facilities.

The most critical one is a new surgery and radiology wing for the Clinical Center, which currently is in a pretty dilapidated state. We have even had situations where leaks happen in the ceiling in the operating room in the middle of a procedure. Obviously, we can't keep that going.

So I appreciate very much your invitation to talk a bit more deeply about that to see if we can bring this back up to being the finest place that it possibly could be.

Mr. COLE. Thank you, Madam Chair.

Ms. DELAURO. Sure. Thank you. Congresswoman Lowey.

The CHAIRWOMAN. Thank you again for being here. Some of us have been working on these issues for a long, long time, and if it were up to us, we would keep raising that number, as Mr. Cole knows.

Dr. Tromberg, I am particularly concerned about a lack of early detection tools for certain cancers, in particular kidney and pancreatic cancer. I understand your Institute is supporting research related to point-of-care technologies, which may be used for more efficient diagnosis of some cancers. If you could explain some of those technologies, what advances in detection are on the horizon, I would be most appreciative.

In one of my visits to one of the New York hospitals, we were talking about just this issue, and I said, well, why can't you—Mr. Murtha, a former, may he rest in peace, Member of Congress, used to tell all of us we should get a scan every year so we know what is happening everywhere.

Is that the reason? Is it cost that we are not doing more of this? Or could you respond to me with a technical response?

Dr. TROMBERG. Thank you, Congressman Lowey. There are so many things that are happening that are super exciting. So I will try to condense this as best as I can.

In general, there is really a revolution going on in micro and nano devices, such as some of these that I have brought with me, an optofluidics device that can analyze body fluids for cancer components. So you have heard of liquid biopsies. We are able to detect DNA from cancers. We are able to detect proteins, tumor-associated antibodies.

We know they exist, but we need the technologies to be able to measure them quickly at the bedside with very, very sensitive hardware and computational approaches. These are some of the things that are going on, liquid biopsies.

We are also developing imaging technologies at the point of care. So what does that mean? Can we have a personalized ultrasound, for example, at the point of care like this one that we have helped develop? Or do we have optical sensors that can measure tumor metabolism right at the bedside and see how patients are responding to chemotherapy, and here is one of those that is under development.

There are also sensors that can be implanted in you and follow whether or not you may have cancer and then deliver lifesaving vaccines or therapies like this microneedle patch. So this is a platform technology of disposable microneedles that once they go inside you painlessly, and they can be delivered to your home. They go inside you. You can't see the needles. And they deliver what their payload is, and then the needles disappear. And then you can get another one in the mail, and you can do it again and again and again.

And they can be built with very smart chemistry inside them to be able to sense things and then deliver the therapy. So closing that feedback loop.

So there is an explosion of technologies. Big imaging technologies as well are improving dramatically, and there will be a time where we are able to go into scanners and have full-body imaging and be able to see early-stage disease. This is coming. This is actually happening through your investment and support.

THE CHAIRWOMAN. I have a little more time. How widespread are these technologies being used now? Are they just at the NIH, Dana Farber, MSK in New York? How widespread are these technologies?

Dr. TROMBERG. So we have—thank you for that question. We have mechanisms to try and dramatically expand this. So we have 30 advanced biomedical technology centers that we, at the NIBIB, support all around the country. Many are developing these technologies.

We have five point-of-care technology research centers that are networked and coordinated. So this is where the discovery and the validation is occurring. They are also all deeply engaged in the dissemination and the movement of the technologies, as I mentioned before, from the blackboard to the benchtop to the bedside, ultimately for commercialization.

So we work very closely with the FDA in order to ensure that once these things are validated, they actually get out to impact the most number of people.

THE CHAIRWOMAN. This is quite extraordinary, 53 seconds. We have been talking before about the translational science spectrum includes turning observations found from basic, preclinical, clinical, clinical implementation, and public health research into tangible intervention.

I just wonder—maybe I should go back to Dr. Collins because we used—or whoever else wants to answer quickly, or with the permission of the chair, you can all answer. Because I can remember very clearly years ago, no names, having these discussions with a former person who had your position who was totally focused on basic research.

So do we have another couple of seconds if someone else wants to answer this?

Ms. DELAURO. Very few.

Dr. COLLINS. I think probably the NCATS Director would have an appropriate response to this.

Dr. AUSTIN. Well, I certainly appreciate the question. You know, from our vantage point, basic research is, of course, absolutely critical. That is the seed corn that we translate. But it is necessary, but not sufficient to get treatments and cures to people.

And the focus that we have is on how slow that process currently is. You probably know it takes around 15 years to go from a fundamental discovery to a treatment that is approved, and another 15 years to get it to all the people who can benefit. And the success rate is less than 1 percent.

And that is one of the reasons why this thing takes so long, this effort takes so long and costs so much. And what is interesting about that process is that we just don't understand it. We don't un-

derstand the fundamental science of that translational process. It has never been studied as a science before, interestingly. And that is what NCATS is doing.

So we are firm believers that like every other science, whether it is engineering or genetics or data science, once we understand the fundamental principles of the translational process, it will turn this from a trial-and-error phenomenological failure-prone process into a predictive science. And that will bring the promise of all of this basic research to people.

The CHAIRWOMAN. Thank you, Madam Chair.

I just want to say one more word because having been on this committee a long time, I think the hardest thing to do with regard to that issue is how you identify and prioritize.

Dr. AUSTIN. Yes. [Laughter.]

The CHAIRWOMAN. When you get past the basic research, then where do you go? But I will save this. I won't take any more time.

Ms. DELAURO. Congresswoman Herrera Beutler, welcome back.

Ms. HERRERA BEUTLER. Thank you, Madam Chair and full committee chair. It is a pleasure to be here.

You know, of course, we could all sit here and talk to you all for a long, long time. I was bummed to miss last week. I was flying back from the district. Otherwise, I would have been up.

But I notice that there are different folks here than generally when you come, which I love. So you are getting us a full circle. There is a couple of pieces I wanted to try and hit.

The first one, you know, how you identify and then turn it into I think what she would say—identify where to spend the money and then how it gets down into that. You know, we have had some conversations around Down syndrome research and making sure that the funds follow the congressional intent. The other piece on that, you know, I was asked to cosponsor, which I will be, a childhood cancer bill with regard to research.

And what the bill does is it would ensure that Federal funds for pediatric research match the same percentage of the number of American citizens under the age of 18 as part of the general population.

One of the things we have seen in our hearing from different areas, I hear it from disease groups, is that the piece that goes into children's—treating children's diseases or research on childhood cancer, for example, tends to lag behind, obviously, the adult population, even if it is a higher incidence in a younger population.

I am wondering how—and this might be a translational piece—how we make sure—our job hasn't been to dictate, okay, this is where you are going to do all the research, and this is how you are going to fund it. We are not the scientists. You are. So we have given that responsibility to you.

However, when we have constituents who come back to us and say, well, we don't see that the money that we are helping, you know, is actually trickling down proportionally. Help us either answer that question or make those changes, and I will throw that to you, Dr. Collins, to give to whoever.

Dr. COLLINS. It is a great question, and I will start out, maybe figure out a way to draw at least one other person in on this.

Certainly, we are completely in accord of the importance for focusing on childhood cancer research, given how incredibly painful and tragic these diagnoses can be, and where we still have many of these childhood cancers that we have not been able to find cures for. Let us point out that, happily, for many of them like leukemias, we have done extremely well. But we need to do that for all.

We currently spend \$514,000,000 a year on childhood cancer research, but that just counts the part that you can say this is research that we know is directly relevant to that. Many of the advances that have happened in children's cancer have come from unexpected directions, and a lot of it from very basic science, just understanding what makes cells divide when they are not supposed to because that is really what cancer is.

So if you really tried to add up all of the things that are probably relevant, it would be a larger number. But I understand the concern of advocates who feel like there is still more that needs to be done.

I was pleased that this committee put an additional \$50,000,000 in your mark for fiscal year 2020, and we certainly will find lots of ways to take advantage of that.

It would be the case, I think, though, that the advances right now that are happening in terms of genomics have opened up new potential. The Pediatric MATCH trial, which now makes it possible for children with otherwise not treatable solid tumors to get into a very creative clinical trial mechanism, is making it possible for lots of these new ideas about therapies to be tried out in a very efficient way and access being offered to those who need it.

Maybe I will ask Dr. Austin to just say a word because I know NCATS is working on DIPG, which is one of the most frustrating and horrifying—

Ms. HERRERA BEUTLER. That is a great example.

Dr. COLLINS [continuing]. And tragic circumstances, diffuse intrinsic pontine glioma.

Ms. HERRERA BEUTLER. And I want to hear about this briefly, but then I also want to ask a question over here.

Dr. COLLINS. Okay. So, Dr. Austin, quickly.

Ms. HERRERA BEUTLER. Thank you.

Dr. AUSTIN. Just briefly, DIPG stands for diffuse intrinsic pontine glioma. It was an absolutely horrific childhood cancer with a very, very short life expectancy in months, and we have teamed up with a number of academic investigators to develop and deploy a new way of identifying combination treatments that will be—that will treat these children.

And as we know, very rarely does one drug treat these children, and it has been a trial-and-error process to figure out how to do those. And those children don't live long enough. And so we have developed a novel technology at NCATS that we are developing with academics and with the NCI that allows us to take those cells from the children and screen across tens of thousands of different combinations very, very efficiently and then deploy those very rapidly in the clinic.

Ms. HERRERA BEUTLER. I have a constituent who is taking part in that and am excited to see the progress.

Really briefly, so what you are talking about with all these different devices, and you totally lit up—clearly, you are—it is almost like the Silicon Valley space because like why not? Let us do it. Let us make this work. Which I appreciate very much because I feel like we often are way slower than that.

Speaking of slow, is the FDA—so with all these promising technologies and to her question about, okay, how do we get these out? How do we get this working? What is the biggest slowdown that we could help with? Because, obviously, we have been working on the money piece—and within like 2 seconds.

Dr. TROMBERG. Yes, thank you. This is a great question, and I, as a technology developer, and all of the community that I represent, we think about this a lot. So we have sat down with the FDA many times and have tried to identify bottlenecks, and some of these are quite famous. We all know about “valleys of death.”

One of the ones that we have worked with the FDA to try to understand is how do they develop standard reference methods to evaluate the 25,000 or 30,000 new applications for devices that come in? Every one that comes in has a validation method, and so that gives them 20,000 different validation methods.

So we are working with them to identify and validate validation methods. So this can potentially increase the throughput. We are also working to develop and fund prototypes. Because you can have a device, it may look cool. This is a pretty good prototype. But in the end, we want it to look like this.

So we have to get to the prototypes faster, and then we have to have these validation methods that are more uniform and applicable to all classes of devices.

Ms. HERRERA BEUTLER. Thank you. Thank you, Madam Chair.

Ms. DELAURO. Thank you. We also have to make sure that we don't cut corners in terms of devices so that we put people at risk. That really has happened over and over and over again. We need to take a very, very hard look.

It is great to get something to market quickly, and I will make reference to e-cigarettes and so forth, without any premarket review. And there we go, in terms of difficulty and deaths. We are not talking here a park or a road. We are talking about people who potentially can die. So we have to be careful in cutting those corners.

Let me—Congresswoman Lee.

Ms. LEE. Thank you very much.

Thank you, Dr. Collins, for being here. Thank your team. It is always good to see you and to know that you are continuing with this life-affirming and lifesaving work.

A couple of questions I would like to ask. Well, I have three that I am going to try to get in.

First of all, let me just mention this request that we had made in terms of the participation of black men in the medical profession. We inserted into the report language in 2019 to coordinate with NIH to review the proceedings of a joint workshop on this topic because, of course, African-American men in medical schools are very underrepresented. And so I just wanted to get a status on that because we hadn't received the report back.

Then my second question has to do with Dr. Langevin. I want to thank you for being here. I have witnessed the benefits of complementary and integrated health as it relates to pain management, also as it relates to preventing—as an alternative to surgery.

My late mother, who I mentioned in this committee, had COPD in her latter life, and thank you for the action plan, and we are following that. But when I was a child, my mother went to a chiropractor. I mean, this is in the like late '50s and '60s. And it worked.

Secondly, when she was in her mid-eighties, she needed a knee replacement surgery in her left knee. She—in her right knee. She got the surgery, and it was fine. But when she turned 89, she needed her left knee, and the doctor said because she had COPD, high risk, blood pressure—high blood pressure, he didn't recommend it.

One day, she was out, and she was in a lot pain, getting her walker repaired, and a woman—and she was complaining about her knee—gave her some lotion. And she tried it, and she never was in pain anymore. And I would call her and just say, "How is your knee?" And she said, "It is drunk."

This was cannabis lotion. So I have witnessed at least my mother and other senior citizens, the health benefits of cannabis. So I don't know if NIH is authorized to conduct research on cannabis, but I know good and well, based on personal experience, that it works for some people.

And then, finally, let me just ask you about the HIV/AIDS strategy and the funding, and hopefully, we will really see our goals of ending HIV and AIDS by 2030. And so I want to thank you all for your continuing work and just want to know how this is going to work now that we are going to increase the funding for domestic AIDS, for our domestic PEPFAR and, hopefully, will end it soon.

Thank you.

Dr. COLLINS. Thank you. Dr. Pérez-Stable would like to start with the first question.

Dr. PÉREZ-STABLE. Well, the situation of diversity in the scientific biomedical workforce, as well as the clinical medical profession, is a dire one. And I agree with you that we face an urgent crisis to diversify our professions. Black men in particular are notable here, but it is across all underrepresented minority—race, ethnic, minority groups.

We have empirical evidence that more clinicians of these groups take care of more poor people, more people that look like them, people who don't speak English. And this has been consistently shown in three different studies over the last 30 years.

Whether the scientific workforce also benefits from this diversity, we don't know. But Dr. Hannah Valentine and others at NIH are working on this.

Ms. LEE. Sure. But the National Academy of Sciences and Engineering, they had a report that came out and had a joint workshop, and we put into the bill we wanted you all, NIH, to work with the Academy and report back in 180 days what we were going to do in terms of increasing the representation based on the recommendations of the 2017 workshop.

So I would like to make sure we get that report as soon as possible because this is a dire situation.

Dr. COLLINS. Yes, I agree. It really is a very serious concern. We are working with HRSA on that, as you can imagine, since this is a critical part of their agenda as well, which is training of the medical professional. And we will get back to you.

Ms. LEE. Thank you. And Dr. Langevin.

Dr. LANGEVIN. Well, thank you for the question about cannabis. Certainly, it is available now. People are using, for example, CBD in the form of oils and lotions, and the public is using this.

And so we are essentially now playing catch-up with what is already happening. We need to understand the potential beneficial effects of some of these compounds derived from cannabis and particularly for pain. There is a lot of potential there. NCCIH has just funded seven grants for looking at the basic mechanisms of cannabinoids and minor terpenes, what we call the different components of cannabinoids, that could be useful for pain.

And we really want to understand how it works, but also we are very interested in looking at potential interactions of cannabis with drugs. Because when people take these cannabinoids—or CBD—with medications, there can be some problems.

Ms. LEE. Sure, yes.

Dr. LANGEVIN. So we need to understand that as well.

Ms. LEE. And it is important, but since so many States have passed medical marijuana laws now, we need to catch up with NIH, and I want to find out legally can we do that? Or how can we help you catch up with where the States are in terms of their—

Dr. LANGEVIN. Yes. Well, the issues of regulation is a broader matter I am going to defer to Dr. Collins on that.

Dr. COLLINS. Yes, we do have a problem in that because marijuana is Schedule I. It is difficult to set up research programs, and we have certainly been talking about the need for some kind of an alternative pathway so that we could do research on potential valuable uses of marijuana without going through such an incredible bureaucratic rigamarole that it scares away most investigators from even doing the work.

And we could use some help from Congress in coming up with a better strategy about that part.

Ms. LEE. Thank you, Madam Chair. I would like to work with you on that for our next bill.

Thank you again very much. Thank you for being here.

Ms. DELAURO. Congressman Harris.

Mr. HARRIS. Thank you very much.

And you will be pleased to know we have a bill filed that it does exactly that. It has been bouncing around for a couple of years. Hopefully, it has some legs that will make research into the potential beneficial use of medical marijuana much easier before it further expands with, I think, a lot of false hopes.

Dr. Langevin, you are absolutely right. There are definitely interactions. In fact, published just last week in the anesthesia literature was a study that looked at people who used medical marijuana, whether or not they had more or less pain after joint surgery, and found out that they had more pain after joint surgery.

Clearly, this is not a drug that acts only on its own. It clearly interacts with other systems in the body, including the analgesic systems in ways that we don't fully understand.

But I am going to ask a question on a very different topic, but it is a very timely question because next month, the *Harris Funeral Homes v. EEOC* case will be heard a couple blocks down, the Supreme Court, which, of course, involves sexual orientation and gender identity. And as you know, Selina Soule and Alanna Smith, two female runners in Connecticut, have filed a complaint with EEOC about gender identity issues with sports.

Now my daughter is an all-American Division I athlete. I have talked to her about this issue, and she just can't understand how you could possibly have men competing against women in a women's sport.

But let us talk about medical research now because a lot of times before this committee, you have said, yes, it is very important. We study men, and we study women. When we look at something, we should be studying men, and we should be studying women.

So I have a very simple question. If you have a transgender woman who would like to participate in a study, are they going to be assigned to the men or the women? And Dr. Collins, I guess first question is to you because sex is genetically determined 99 percent of the time. That is what I learned in medical school.

Now maybe I am wrong. Gender may be different. But in fact, when you are doing this research, is it sex or gender that is important? Where are the differences? And how would you do that?

And in fact, if you say, well, we are just not going to assign that person, isn't that discrimination against them? And depending upon what the outcome of this case is, where does this stand at the NIH?

Dr. COLLINS. Very important issue and, obviously, a very timely one. And we noted with interest and concern a few years ago, the Institute of Medicine's report on health of individuals who are LGBT, and it is clearly an indication that this is a circumstance that is associated with bad health outcomes, particularly in terms of mental health issues, depression and suicide.

So we took that very seriously and actually have set up at NIH a Sexual/Gender Minority Office to try to be sure that we are paying attention to what the research needs might be to try to better understand that as a health disparity.

Mr. HARRIS. Excuse me. Can you just define what a sexual minority is? I am not sure I understand. I understand a gender minority. Can you define a sexual minority?

Dr. COLLINS. I am not sure I want to try.

Mr. HARRIS. You are a scientist. Look, this is science, and we hear all about science deniers and all. What is a sexual minority?

Dr. COLLINS. I think at the present time, without trying to be too precise about it, most people would say those who are not in a traditional heterosexual role would be considered a sexual minority, and that would be LGBT and others in that category.

Mr. HARRIS. So as a scientist, you believe that sex is not binary and 99 percent, it is not based on genetics?

Dr. COLLINS. I believe that sex assigned at birth is very heavily, probably 99 percent or so, influenced by genetics. Let us not forget,

though, there are individuals who are born with ambiguous genitalia where sex is not obvious.

Mr. HARRIS. I was very specific. I said 99 plus percent. I didn't say 100 percent. I am being very—this is serious because our colleagues in the third branch are going to have to rule, I think, on what some people feel is a scientific question, the definition of sex.

Now they may also rule on the definition of gender, I am not sure. But the law, Title VII, which is what is under review by the Court, uses the word "sex." And as a scientist, I want to ask you what is the definition of sex?

Dr. COLLINS. Again, as I said, I think at birth, sex is highly, 99 percent associated with the genetic measure of whether there was an X—whether there is an XX or an XY chromosomal constitution.

But let us be clear. Biologically is one thing that one's actual personal identity can be in a different space. I think that is a very complicated issue that I am probably not saying anything particularly novel or illuminating about in this conversation, but one that needs to be respected for those individuals who find themselves in a circumstance where they are not comfortable with their genetic sex—

Mr. HARRIS. So how will NIH, which study will the—arm will the NIH put a transgender woman into? The male arm or the female arm?

Dr. COLLINS. Well, it might be that that study was actually looking at transgender women and trying to understand—

Mr. HARRIS. Dr. Collins, if it is looking at the metabolic studies on female collegiate runners, is a transgender woman going to be assigned to the female or the male branch? And if they are assigned to the female branch, isn't there a risk that it makes the study less valuable and applicable to female runners?

Dr. COLLINS. I don't have an easy answer to your question.

Mr. HARRIS. Thank you very much.

Dr. COLLINS. I think most of my studies would ask for sex assigned at birth.

Mr. HARRIS. Thank you very much.

Ms. DELAURO. Congresswoman Roybal-Allard.

Ms. ROYBAL-ALLARD. First of all, Dr. Collins, let me just say thank you for a truly informative and very hopeful tour last week of NIH—

Dr. COLLINS. So glad you all were with us.

Ms. ROYBAL-ALLARD [continuing]. And I just want to say that I also share my concerns about the infrastructure that we talked about and look forward to working with you on that.

Dr. Pérez-Stable, as you mentioned, research has not always been inclusive of certain population groups like racial and ethnic minorities, and this has resulted in treatment and healthcare practices that do not work with the same effectiveness for everyone. The All of Us research initiative has the potential to radically change what we know about minority health and how we approach the elimination of health disparities.

What was NIMHD's role in the development of the All of Us initiative, and how are you currently working to recruit and retain diverse and inclusive minority populations in this research program?

Dr. PÉREZ-STABLE. Thank you, Congresswoman, for that question.

So I arrived at NIH just as All of Us was being conceived. So the Precision Medicine Initiative was all the buzz when I got here 4 years ago, and I have been supportive and enthusiastic supporter of the cohort study and, in fact, have been one of the Directors who have worked with Eric Dishman on his “kitchen cabinet” of IC Directors.

So we are very enthusiastic about it. First, on the fact that it will be a tremendously rich research resource for future investigators. It already is the largest cohort study of Latino participants and African-American participants in the country, although it is not yet fully developed, over 200,000 fully enrolled. And so we are very, very supportive of it.

I would add that the inclusion of diverse participants in NIH clinical studies has actually improved a lot. So we are about 30 percent now and that one of the problem areas have been in genetic studies, and we are working systematically to address that.

Ms. ROYBAL-ALLARD. It seems to me that there are multiple opportunities for NIMHD to consult and to collaborate with other Institutes to help to define a better focus on health equity and to ensure appropriate minority representation in clinical trials. What unique portfolio has NIMHD defined for itself in the 10 years since it was elevated to an Institute? And can you give us some examples of research studies that are being led by NIMHD?

Dr. PÉREZ-STABLE. So thank you again.

Our involvement with other Institutes is full. I have met with all of them. We have common areas with every single Institute and Center on the NIH campus. We have, for the last 4 years, been working on redefining the categories of minority health/health disparities, how these apply, going through a detailed scientific visioning with NIH scientists, as well as extramural scientists, and have a strategic plan for all of NIH that we have led for minority health/health disparities that is almost completed.

It needs just to go through the final clearance processes. So I have presented to the Institute Directors and have worked with them on.

Now we, NIMHD participates in several important NIH-wide programs. We co-fund the Jackson Heart Study and the Hispanic Community Health Study out of the National Heart, Lung, and Blood Institute. We work closely with National Institute on Drug Abuse on the ABCD, the adolescent cohort study. And just we agreed to continue supporting that.

We have been part of the Centers for AIDS Research that primarily are funded through the National Institute of Allergy and Infectious Diseases.

We also, when we put out a call for our own research community, we asked other Institutes are they interested, and we had a terrific participation for a very timely post-Hurricane Maria research in Puerto Rico that had to be from Puerto Rico. And we had six different Institutes agree to set aside money if they got applications that were in their area. And sure enough, National Institute of Mental Health, National Institute on Drug Abuse, and National Cancer Institute, and National Institute on Aging all had applica-

tions that they funded, along with the 9 or 10 that we funded ourselves.

Ms. ROYBAL-ALLARD. And just one final question. I understand that there have been some challenges with the NIMHD research endowment program, and I am not going to elaborate on what those are. But has that been reinvigorated, and how does the endowment program contribute to the mission of your Institute?

Dr. PÉREZ-STABLE. So, briefly, the endowment program is money that the NIH provides to an institution that to be eligible has to have less than the 25th percentile of the average endowment for academic institutions. That they need they have to bank for at least 20 years after the end of the grant.

So the amount varies. Right now, it is at \$2,000,000 per year. They can get it for 10 years. So you can do the math, \$20,000,000. They use the interest to develop programs that promote their research capacity in minority health/ health disparities. Most of the institutions are working on issues around training and other sort of infrastructure that relate to research, not administrative work.

We have gone through—our advisory council went through a review in the first year I was here, and there are no restrictions on applications. Right now, our budgetary allotment was full, but in fiscal 2020, we will have another Funding Opportunity Announcement, and there will be no issues with eligibility.

It has been linked to having a Center of Excellence funded either from HRSA or from NIMHD. And we believe that is a limitation that will actually limit the number of institutions much more than anything else that we have.

Ms. ROYBAL-ALLARD. OK, thank you.

Ms. DELAURO. Mr. Moolenaar.

Mr. MOOLENAAR. Thank you, Madam Chair.

Dr. Collins, welcome back, and great to see everybody here today, and thanks for participating.

I had a couple areas I wanted to ask about. I know in May, there was a symposium that NIH participated with the USDA, looking at a collaboration on research opportunities that may lead to translational benefits in other fields looking at animal research and how—and specifically on farm animals. And I am just curious as to kind of where you see that going and maybe what benefits might come out of that?

So that is one area I wanted to talk about, and then the other area I wanted to ask you to address is antimicrobial resistance and kind of what our strategy is for combatting superbugs, if you will?

Dr. COLLINS. Thanks. Those are both great questions, and I will start. If others want to jump in, they should signal me.

Basically, you are quite right. There are great opportunities for looking at health issues by comparing what happens between animals and people. We are all rather similar when you start looking closely at various metabolic pathways and illnesses that can happen.

Certainly, we at NIH have tried throughout many decades to try to build on that, and certainly, there are many instances where illnesses that we want to understand in humans, a model appears in a farm animal, and we can learn something from that, both in

terms of what the actual mechanism is and what possible treatments might work.

So, for instance, right now, we are having great concern about EEE, this Eastern Equine Encephalitis, which has had a particularly bad outbreak in a few States and has killed some young people and some middle-aged people. And that is, of course, really a disease of horses, and the more that we can understand that.

Interestingly, there is a vaccine in horses, but there isn't yet one in people. So go figure. There is an interesting story behind that somewhere.

So I totally agree. And USDA has been a wonderful partner in this. They have a great interest in research, although an awful lot of their dollars go into other service activities that they are required to do.

Certainly, this also applies not just to farm animals, but also to other animals. Certainly, I am thinking the very first effective gene therapy for a human disease was for an eye disease called Leber's congenital amaurosis. The reason we knew it was going to work because there was a dog model, a spontaneous example that happened in a particular dog.

Some of you might have met that dog 10 years ago because it took quite a tour through the Capitol after having the therapy work in the dog, and a couple of years later, it worked in the kids. So we get it as far as this interaction.

Antimicrobial resistance continues to be a vexing and deeply troubling problem because of the way in which so many instances are happening of organisms that are resistant to all known antibiotics, which are causing outbreaks particularly in hospitals. We have done a lot to try to be sure we track those down quickly in hospitals by providing the kind of diagnostics necessary to understand the transmission.

Basically, there are two problems here. One is the overuse of antibiotics that has caused these resistant organisms to appear, and the other is the market failure where essentially the development of new antibiotics has not been appealing in the private sector.

NIH's role, and this has been in part supported by this Congress by providing resources, is to try to be sure we are doing everything we can to develop that next generation of antibiotics to take it further down the pathway toward an actual approved drug than we normally would have to, to try to de-risk these projects so that an industry partner will decide it is worth taking it up, even though they know there are not going to be a lot of profits there.

I think that is making progress, but I think we are still well behind where you would want to be to say that this is a problem we have solved. We have not.

Mr. MOOLENAAR. Is there—okay, go ahead.

Dr. BRENNAN. If I may? You may be surprised that the National Library of Medicine is playing a role in some of this integration of antimicrobial approaches. One of our researchers, Eugene Koonin, is an evolutionary biologist who uses computational methods to understand how these germs actually change over time to determine if there is a point of intervention that may happen earlier in the cycle.

Thank you.

Dr. AUSTIN. I just wanted to add one thing about the animals. We have a collaboration among 12 of the Nation's veterinary schools with the same number of CTSA hubs who are working on diseases in common between humans and animals to see what we can learn by studying those together.

And as a matter of fact, next week—actually, this Thursday—at the CTSA annual meeting, we are having a speaker, a representative from the USDA come and talk to the entire group in order to figure out how we can expand this approach.

Mr. MOOLENAAR. Thank you very much.

Dr. TROMBERG. Can I also add that point-of-care types of platform technologies have traditionally moved in from humans into animal care as well, and this is a great opportunity for further growth, both from the bedside diagnostics, for example, of bacterial infections, doing that rapidly onsite by owners in their—wherever they need to do this, as well as interventional approaches like the microneedle vaccine that I was just showing you.

Ms. DELAURO. Thank you.

I would just say to my colleague the issue of animals, we need to take a hard look most recently at the rule that was approved by the USDA in dealing with lessening the inspection force in our—on swine slaughter and also with line of speed, there is taken off the cap. So right now, the inspector has about 4 seconds to look at any animal that is going by and so forth.

So if you just don't cap the speed, it is going to be very little ability to deal with that. The second part of it is with the FDA and the regulation of the use of antibiotics in livestock, a serious issue, John. And you are thoughtful about this. Take a look at it because, in fact, we are allowing—we don't allow it for growth promotion anymore, antibiotics.

We have to have—if there is a sick animal, we need to have a veterinary provider prescription. But we have left a gaping loophole, which says that it is the—we can use antibiotics for prevention, and that has opened up unbelievable because of the way we are dealing today with a herd of 5,000 swine. It used to be 150 and 120. They are prone to illness or disease. We take care of that, but we are also using antibiotics for prevention.

That means that you buy a pork chop. You get it. You get ill. We are then not able to treat you, or we treat you and it is resistant because it is the same thing.

Longer than I wanted to go, but you need to check with what is going on at the Department of Agriculture and with the FDA on what is a very, very serious issue. Sorry, guys. I just—we did something about about it in the ag bill here. We said you couldn't use—we put a limitation on doing this, but the Senate hasn't approved it. So we will see where we go.

Congressman Pocan.

Mr. POCAN. Great. Thank you, Madam Chair.

And thank you all for being here. And sorry I missed the testimony. I had two meetings back-to-back, but I did hear and I was very happy to hear that funding for first-time investigator researchers is up considerably, and this year, we are going to have

another record. So I am very happy to hear that, and people back home will be very happy to hear that.

Back in March, Dr. Collins, I had asked a question about there is a study that the—or an update from the National Academy of Sciences that had a report from 2011 to 2016, every single drug approved by the FDA had NIH support. I think I asked at that time, was there an update?

I am going to ask my question again because I really, really would love to have an update on that. Is there an update on that study yet that you can share?

Dr. COLLINS. That is a very important study published in the Proceedings of the National Academy of Sciences. The senior author was Fred Ledley, and they studied all the 210 drugs that were approved by FDA between 2010 and 2016 and concluded that 100 percent of them had had significant input from NIH-funded research in order to get to that point of having an FDA-approved therapy.

This was not funded by us. That study was funded by the National Biomedical Research Foundation, which is a private foundation. I suspect they might be interested in renewing the effort, and we can reach out to them and see if they would like to—it is almost better, I think, if this is something that is funded not by us because it will seem less self-serving.

I suspect that the answer will be very much the same. I mean, the way in which our ecosystem works where the kind of NIH-funded basic science and translational research gets handed off to industry for them to actually turn into an FDA-approved product has been the envy of the world, and it is very successful. And I think it probably hasn't changed in those last 3 years.

But I will reach out to that foundation and see if they would like to update that study.

Mr. POCAN. I would really appreciate the nudging because especially now this is an issue that people talk about back home, we are talking about in Congress. It would be very valuable. So thank you.

Another question. In July, the administration made changes to the NIH requirements regarding proposed human fetal tissue research, and one of the changes was to implement an ethics advisory board. I think it said something about no fewer than one-third, no more than one-half shall be scientists with substantial accomplishments in biomedical or behavioral research.

I have researchers like back in UW–Madison, who conduct this critical research, and they would like some clarity on the guidelines for the selection process for the advisory board scientists. Specifically, will there be an effort to appoint scientists to the board who have substantial experience or substantial accomplishments in research involving fetal tissue?

Dr. COLLINS. You are quite right that the new guidelines require the establishment of this ethics advisory board, and its constitution is basically laid out in legislation from 1993. So this is not a new formula, and it does say between one-third and not quite one-half of the membership should be scientists without particularly specifying exactly what disciplinary expertise they have.

The appointments are to be made by the Secretary of Health and Human Services, Secretary Azar, and this is the moment, I think, where ideas are being put forward about what would be an appropriate roster for that, for us at NIH. We are obviously very interested in seeing this get up and going so that additional applications for human fetal tissue research can go through this additional level of review.

That is going to take some time, and so it will mean over the course of the next several months that we won't be approving such applications. But if the board gets set up and can be constituted in such a way that they can review these in a timely manner, then that is what we expect will happen perhaps in the next year.

Mr. POCAN. Any idea on their timeline or—

Dr. COLLINS. I couldn't really guess at it at the moment.

Mr. POCAN. All right. And then, finally, a question on autism, specifically on autism as it relates to people who are transitioning from essentially youth to adult ages. There was a report, I know, that came out from Interagency Autism Coordinating Committee that said about 2 percent, or actually, less than 2 percent of the combined Federal and private autism research funds are going to that specific population of people who are transitioning to adulthood.

I was just wondering if there are any opportunities for additional investment in research regarding adults with autism, and any additional investment in understanding the issues regarding the lifespan of people with autism?

Dr. COLLINS. Certainly a very appropriate question, and I think most people, when they hear the word "autism," they are not necessarily thinking about this group of individuals who are entering adulthood, many of whom actually would tell you that they don't really appreciate being considered in the same boat as a child with autism who needs a lot of interventions. Many of these are highly functioning individuals.

We are certainly looking at that. The NIH, particularly the National Institute of Mental Health, has a very vigorous portfolio in autism, and through the IACC that you mentioned, this kind of opportunity for thinking about the priorities in that portfolio is what comes up. And Dr. Josh Gordon, who is the head of that, is no doubt considering that.

Dr. Brennan.

Dr. BRENNAN. Yes, Mr. Pocan, I would like to also comment. The National Library of Medicine is actively working in two areas related to this.

One is we have a researcher at the University of Cincinnati and Children's Hospital who is working on creating the proper integrated medical record for children aging out of supervised care into individualized care. And although it doesn't specifically address the issues of autism, what we are learning from that is how a young adult, and the emerging adult, moves into self-management of health information.

The second piece is we are working with using innovative technologies to bring into adulthood some of the tools that may be necessary that are less stigmatizing in terms of the illness part of autism, but interpreting social cues and understanding. So using vis-

ual technologies to help a person who is trying to function in their adult life get the cues that they need to be able to continue to work there.

Mr. POCAN. Thank you very much.

Ms. DELAURO. Congresswoman Frankel.

Ms. FRANKEL. Thank you all for being here, and I enjoyed my visit the other day.

I want to follow up first with Dr. Tromberg, and I might be asking you something you already said. But sometimes, you know, when you hear something for the first time, it doesn't really penetrate.

So on the imaging, is there anything new on the mammograms that is going to lead to women not having to have those regular mammograms all the time? Or the—

Dr. TROMBERG. Yes, thank you. Thank you for your question.

That is a very, very active area of research in our community. There are number of things going on.

First, just in terms of mammography, there is a lot of work to improve mammography itself and develop new computation-based techniques to help us read mammograms better. There are other technologies using x-rays called digital breast tomosynthesis that give you more of a three-dimensional view and give you a better appreciation for detection and diagnosis.

Then there are alternatives to mammography, like the one that I mentioned using lasers, very short pulses. They can create sound waves deep inside breast tissue so you don't have compression and contrast agents and so forth.

There is enormous amount of activity in the MRI community, and using artificial intelligence, we can actually do MRIs faster and more inexpensively so you can reap the benefits of an MRI but possibly do it with smaller and more compact devices.

So this is a very, very active area of engagement in our technology development community and definitely one of our target goals.

Ms. FRANKEL. So where are you in terms of something really being out there to the public so you don't have the compression mammograms?

Dr. TROMBERG. All of these technologies that I just mentioned are actually in various streams of both clinical studies, entirely computational studies. So another really amazing advance is that we don't even have to build some of these technologies. We can model them and then do simulated clinical trials—and the FDA has just recently published a paper doing that exact thing, comparing digital mammograms with digital breast tomosynthesis and just said, "Hey, which one is going to work better?"—before we go out and do expensive clinical trials.

The MRI studies are ongoing in our centers all around the country. That photoacoustic tomography with the ultrafast laser, that technology is currently being developed and commercialized. So lot of really interesting, wonderful alternative approaches, and they can potentially provide information at all stages of care.

Ms. FRANKEL. So those MRIs, is that going into those claustrophobic tubes?

Dr. TROMBERG. So there are a number of really beautiful advances in MRI in both the magnet technology that are making the magnets more portable, the computation to do image reconstruction. And also, if you notice, there is that big tube, but you also have a coil that picks up the signals after the radio frequency is launched into the body, and then you have coils that pick up the signals from inside the body.

Those coils are being made for individuals now. So breast coils, hand coils that are flexible so that we can look at movements, other types of body coils. So make MRI actually even more compatible and flexible with each of these applications.

Ms. FRANKEL. OK, I don't know whether that you said you still have to go into the tube or not? [Laughter.]

Dr. TROMBERG. Well, I think if we are going to have MRI, we are going to have some kind of a tube. So one of the big advances, though, in brain MRI, just to pivot a little bit, is a small cap that you can wear on your head. And that is portable, you can still move around, and it is just looking at brain.

So as those technologies develop and get out there, they can be translated to other applications such as breast or fascia imaging, as I have talked with Dr. Langevin about many, many times. So wonderful opportunities. As these technologies are developed, they can move into other areas of importance.

Ms. FRANKEL. What about detecting ovarian cancer?

Dr. TROMBERG. This is certainly one of the most difficult things to do. There is a lot of work going on in trying to do what we call liquid biopsies. There has been a number of really exciting advances in being able to both detect and diagnose ovarian cancer during surgery using technologies that take, if you think of medical research, you often think about microscopes.

Imagine you could take the most powerful microscope and turn that into a small, hand-held endoscope and get the same or even more specific and better information. Then you could stick that inside the body and you could help guide ovarian cancer surgery. We know that surgery is still the best therapy for cancer. You can get lots of cells out very, very quickly.

What if you could identify every one of those cells by looking at the same microstructure of the cell that a pathologist uses after you take the tissue out. They go away. They examine it for weeks and then come give you an answer. What if you could get that information at the bedside intraoperatively during surgery and then get rid of all the cancer?

So that is one advance that is going on in ovarian cancer.

Ms. FRANKEL. Madam Chair, if I could just have one more question, which is have you had anybody—have you had any directives from the Trump administration to either discontinue or change research on reproductive health?

Dr. COLLINS. We are all looking at each other like no.

Ms. FRANKEL. I don't want to give anyone any ideas, but OK.

Dr. COLLINS. Of course, there is, as we talked about a minute ago, this limitation on doing research on human fetal tissue. If you want to include that in reproductive health, that would be an answer to your question. I wasn't sure if you were thinking about that.

Ms. FRANKEL. OK, thank you. Yield back.

Ms. DELAURO. Congresswoman Watson Coleman.

Mrs. WATSON COLEMAN. Thank you. And I apologize for not being able to hear all of your testimony. I was in another hearing, but what I have heard and the answers to the questions have been very intriguing.

I want to ask a question about the disparity in health with maternal mortality and infant mortality, and I wanted to know what is actually happening in researching those particular issues.

Dr. PÉREZ-STABLE. Thank you.

Mrs. WATSON COLEMAN. And what resources are applied there, too?

Dr. PÉREZ-STABLE. A critical question of great interest across the agency. First, NIMHD is really establishing collaboration with other Institutes and Centers about this topic, I think being led by the National Institute on Child Health, and we are very much there, as well as with other Offices of Minority Health across the Department.

So we have to think of maternal mortality as a continuum. It is the worst outcome of what we call maternal morbidity. So having sickness or illness as a woman goes through the process of conceiving, having a pregnancy, and delivery. And we look at disparities, the African-American women, the American Indian women have disproportionately high burden of disparity in the maternal morbidity/mortality space.

We have to look at the continuum of what happens at conception, during prenatal care, visiting the hospital and the clinicians that take care of the delivery, and then, very importantly, postpartum what happens. And at each of these places in this continuum, there is opportunity for intervening to decrease these disparities.

African-American women, for example, have greater burden of cardiovascular disease and diabetes when they conceive. African-American women may have a greater risk for developing a thrombosis and deep venous thrombosis, which may lead to clots into the lung.

Mrs. WATSON COLEMAN. So that is really kind of what I am getting at. What are we doing in terms of researching the whys of all of that?

Dr. PÉREZ-STABLE. A lot of it depends on the well, the whys is, you know, is it genetic? Is it behavior? Is it preexisting illness?

Mrs. WATSON COLEMAN. Environmental?

Dr. PÉREZ-STABLE. But a lot of it has to do with the access to the quality of care and the settings where they are getting their care.

Mrs. WATSON COLEMAN. So are we doing intensive research on these disparities on the why, what to do about it, and things of that nature? I want to know—you stated the problem, I agree. I wanted to know what are we doing about those things? Are we initiating research studies? Are we doing whatever one does in this space?

Dr. PÉREZ-STABLE. The process has come very much to our attention. We actually have funded a research grant in New York City that examined this level of continuity of problems, looking at how much was related to the mother's health leading to bad outcomes,

how much was related to the care she was getting, and to the setting she was going to.

Mrs. WATSON COLEMAN. Are you able to isolate the amount of resources that have been identified for looking at these issues? So if I asked for a report on the dollars that are spent in this area, could I get that, Dr. Collins?

Dr. COLLINS. Yes, I am quite sure we could figure out—I am not sure whether it is one of the things that we track in what we call RCDC, where we automatically keep track of dollars. But we can try to see what we can do.

I will tell you this is an area—and thank you, members of this subcommittee, for particularly drawing our attention to this—that all of NIH is now focused on with much greater attention, considering that the trends are all going in the wrong direction.

Mrs. WATSON COLEMAN. Yes.

Dr. COLLINS. And so there is now a trans-NIH group of high-level research leaders, including Dr. Pérez-Stable's Institute and many others, to try to see what are we collectively maybe not doing that we should be in this space. Not just to identify what are the factors, but also to identify possible interventions that could be tested in a research environment.

Mrs. WATSON COLEMAN. So, thank you. These, I guess, first-time investigators, you did 1,287 of them, is that—last year?

Dr. COLLINS. That is exactly right. That was last year, and this year, as of this morning, we are also at 1,287, expecting we are going to break through that ceiling.

Mrs. WATSON COLEMAN. So could you break down for us the racial and ethnic breakdown of those who are these investigators who are getting these opportunities for us?

Dr. COLLINS. I don't have the numbers in front of—

Mrs. WATSON COLEMAN. I know you may not have them now, but—

Dr. COLLINS. I would be glad to provide them.

Mrs. WATSON COLEMAN [continuing]. I am asking if you could prepare—

Dr. COLLINS. I will tell you that there are not as many as we wish there were, but we are working intensively on that. We have an entire set of programs to increase the diversity of our workforce.

Mrs. WATSON COLEMAN. Thank you. Through the chair, if that is possible, not only would I like to know the numbers of the representation, I would like to know whatever efforts are being used.

I have one last question. I have a number of them. This one here I just have to ask. I was told by a doctor that at the age of 75, you no longer get a colonoscopy. Why is that?

Dr. COLLINS. The United States Preventive Services Task Force, USPSTF, is the organization that looks at all the evidence for all kinds of preventive actions to decide whether, in fact, they are justified in terms of benefits and risks. So they have looked at all the studies—and this has recently been reevaluated—to assess what is the benefit of colonoscopy?

And their conclusion is by the time one is 75, if at that point you have not had any identified colon abnormalities, you are not likely to have them in the future. You are kind of—

Mrs. WATSON COLEMAN. OK.

Dr. COLLINS. You are like out of the risk zone and into the clear.

Mrs. WATSON COLEMAN. I just wanted to make sure somebody wasn't thinking, well, you are 75 so—

Dr. COLLINS. So you are not worth it. [Laughter.]

Dr. COLLINS. No, that was not the reason for their conclusion. No, I think it is a much happier outcome.

Mrs. WATSON COLEMAN. I would like to just—I asked the question before, one about autism and what is happening, particularly as it relates to minorities and research. And other one was sarcoidosis. And I just wanted to ask you for updates on those.

And with that, I yield back, madam.

Ms. DELAURO. If we can get those updates, we will be happy to—

Dr. COLLINS. For the record, happy to do that.

Ms. DELAURO. Yes, please, in response to Congresswoman Watson Coleman.

Dr. Langevin, let me address a couple of things here. You talked about NCCIH and the natural products, dietary supplements. These products today are unregulated, as you know. So consumers have to seek out information on the safety and the effectiveness on their own.

This is of particular interest to me, and I will say it here so that it is in the record. I believe that we ought to regulate dietary supplements. Some of the claims are truly outrageous.

But how do you disseminate your research findings to the general public? How do you work with the FDA and other Federal agencies to disseminate the research findings, and what is the outcome? Have we used your research, both positive or in a negative way to say this should stay, this should go?

Thank you.

Dr. LANGEVIN. Thank you. These are all very important questions.

In terms of dissemination, first of all, highly important. We don't want people to be getting the information randomly from the Internet. So NCCIH is very active in maintaining an information list on their website. It is called HerbList. It is actually an app that you can use from your phone. And if you want to look up a specific type of nutritional supplement or natural product of some kind, you can just go and look it up, and you will get the information right there. And that is constantly updated.

The other thing you mentioned is finding out are these products effective? Do they actually work?

Ms. DELAURO. Safe.

Dr. LANGEVIN. And are they safe? Exactly. NCCIH conducted a number of clinical trials—or actually, earlier on, when it was still called NCCAM—on substances like, for example, ginkgo and echinacea, things like that that people were taking, and to find out do they actually work? And most of these trials ended up showing no significant benefit compared to placebo.

What we think, though, it is not a matter that we should just abandon this research. I think what we need to do is actually go back to the lab and take these plants or whatever they are and really go into their basic active ingredients. Look at the chemistry, see whether we can find out in vitro, and then find out are they

actually having effects? For example, anti-inflammatory effects would be an important piece.

If we find these effects *in vitro*, then we can go into an animal model. Find out if they actually work and then test that in the clinical trial. But it is almost like we don't want to just go and pick something off of the shelf at the health food store and do a clinical trial on that. That wouldn't make any sense.

Ms. DELAURO. With that, and I would love to have offline to proceed with this, but this, the whole area of dietary supplements has been left, and I was pleased to read your testimony and what you are doing. But there needs to be serious collaboration with what can go back and look at, look at the properties, see what that relevant to other areas. But there has to be, you know, some defining answer to what is on the shelf, which people are just picking up and using without any knowledge of whether or not this is dealing—is going to address whatever their need is in this regard.

Dr. Collins.

Dr. COLLINS. There is an Office of Dietary Supplements also at NIH, works closely with NCCIH. One of their goals is to make sure that all the information we do have is available in labels. Eighty thousand labels now available on dietary supplements that contain the information we have.

Unfortunately, most of it is pretty incomplete because a lot of it is not based upon any rigorous kind of scientific study. There was a Federal task force last year that pointed out the lack of data on the extent of use and the safety and utility. And I did see FDA earlier this year, back in February, signaling that they thought it might be time to look more closely at dietary supplements. So what you are saying might actually be getting some traction.

Ms. DELAURO. Well, I hope so, but we are going to proceed to make sure it does.

Let me just—because Ranking Member Cole is not going to be able to get back, so I think it is just Congresswoman Roybal-Allard and myself. So I am going to ask a couple more questions and then leave you with time for your questions. Okay?

Let me with regard to the pain research that you are doing, I just want—we are spending, and we should, enormous amounts of resources to deal with the issues of opioids. So your work is critical here, and one of the things that I very much wanted to do was to look at a cross-cutting way of—honestly, today, if you write a grant that says you are going to deal with opioids, you are bound to get the money to be able to do it because that is—it is really a crying need.

But with the kind of research that you are doing, that needs to be overlaid, in my view, on where we are directing our funding. I don't know how far along you are with what you are doing to provide us with some real sound advice about directing dollars to what is appropriate, what will work, rather than just saying, okay, my God, we have got to do something, and here is the money for opioids.

That seems to me, you know, we should not be throwing good money after bad. I don't know what is working or not working. It may all be working. But I think you have a really big piece of the puzzle here to help us to do that.

Dr. LANGEVIN. I would agree. And as I mentioned before, we are conducting a large effort right now in what we call pragmatic trials. So, basically, we take therapies that have been shown to be effective in a controlled setting, say, in a randomized trial compared to a placebo, and then we say, OK, if we put that into a healthcare setting. For example, in the military, we are having a big effort right now in collaboration with the Department of Defense and the Veterans Administration to test behavioral interventions in service members and if veterans to see can this be implemented in that healthcare system, and does it help with pain?

So that is an area where it is very pragmatic. You want to know just the way that these therapies are being delivered in the healthcare setting, do they actually work? Do they actually help patients?

And at the other end of the spectrum, we are investing a lot of effort, especially in our intramural program, in basic pain mechanisms to understand what are the effects, for example, of emotions on pain? We know that the same painful stimulus is very different depending on the mood that you are in. So we need to understand that better.

And some therapies actually interact with that. How opiates, for example, have an effect on the brain is very different depending on if the person is depressed or not. So it is very interesting, and we need to understand that better to understand pain research better.

Dr. COLLINS. Chairwoman, if I may, because this is such an important issue, all of the NIH Institutes have been asked to come up with the most creative possible ideas that we could use to approach this epidemic of opioid overdose and death, as well as the need for nonaddictive pain treatments for the current people who suffer every day from chronic pain.

We broke this down into six different themes that you see as bullets around there, including worrying about neonates that are born addicted to opioids because their mothers have had that issue. That doesn't look like a particularly impressive diagram, but underneath that are more than 40 different Funding Opportunity Announcements that have been issued in the course of the last year and a half, thanks to you because of the provision to NIH of \$500,000,000 a year for this particular initiative, which we call HEAL, Helping End Addiction Long-term.

And we got an outpouring of response from the community. And unfortunately, what you said, not everybody who wrote an opioid grant did get funded. Some of them are still pretty mad at me because, actually, the success rate was more like 20 percent, just like our usual, because there was so much opportunity there.

And it is everything from basic science of understanding how pain works to the HEALing Communities Study, which is moving into four States to try to see what happens if you bring together all of the stakeholders and see if you could actually end the epidemic of opioid overdose deaths.

There will be more announcements about this later this week. So it is a timely question for you to pose. I want to assure you this has been all hands on deck for everybody around this table and all the people you don't see who are also working on it.

Ms. DELAURO. Thank you so much. Congresswoman Roybal-Allard.

Ms. ROYBAL-ALLARD. Well, thank you, Madam Chair, for covering my first question. I appreciate that.

First of all, Dr. Collins, since the administration did not allow the NINR to come before our subcommittee, I do want to raise an issue which I am sure you are very aware of. And while I am very pleased that someone so experienced has been put into position of Acting Director to lead the NINR until you can find a permanent Director, I am sure you are aware that there is a lot of concern regarding the fact that there is not a nurse in that position.

And so what I am hoping is that you will quickly find an outstanding Ph.D. prepared nurse to lead that Institute, and I just wanted to make that point.

Dr. Brennan, expanding the scientific workforce for biomedical and behavioral research and increasing its racial, cultural, and disciplinary diversity is one of NLM's strategic goals and is essential to ensuring that discoveries that lead to healthcare innovations and cures. The question I have is that as the first nurse Director of the world's largest biomedical library, what efforts are you leading at the NLM to build a diverse, educated workforce for data-driven research?

And how are you ensuring that this workforce will include not only physicians and Ph.D. scientists, but also clinical practitioners across multi disciplines, such as pharmacists, nurses, physical therapists, and psychologists?

Dr. BRENNAN. Thank you very much for the opportunity to address that.

First, I would also like to say that I am co-chairing the search for the new Director of NINR.

Ms. ROYBAL-ALLARD. Good.

Dr. BRENNAN. And we are very, very excited about the opportunities. Dr. Perez-Stable is my co-chair with this. So we are off and running.

Secondly, to address the workforce issues, we have started at home first. So we have initiated an internal training program for all the 1,700 women and men who work at the National Library of Medicine to do individual assessments of what are the data science skills that we need across the board from librarians to computational scientists, to computer scientists, and to the clinicians who work with us.

Second, we are helping to lead—across—the NIH the designation and development of workforce competencies that address not only scientists, but also those that acquire and use scientific information, particularly making sure that clinicians have the ability to read and understand and to learn from data science-driven resources.

But finally, we are also funding an initiative that we call personal health libraries that actually directs to laypeople, to patients, to help understand what does it mean to have data-driven discovery?

We recognize that building the evidence for practice from data-driven discoveries is going to require that clinicians need to learn differently about how they interpret evidence. And so projects that

use artificial intelligence to make interpretations of clinical images or make recommendations about how one might expect a care process to occur require that we bring clinicians along to understand how to interpret this information.

So we are looking at model curriculum. We are looking at enhancing the library science workforce around the country in our academic medical centers and health science centers so that across the health science curricula, physicians, pharmacists, behavioral scientists, nurses have access to these data concepts and data-driven discovery.

And finally, we have to recognize that we need not only the Ph.D. prepared workforce and the clinically prepared workforce, but we need community college trained individuals. We need baccalaureate individuals who are able to assist in data preparation, data cleaning. We are developing models of data security to make sure that we can actually safely learn from the data we are acquiring.

Thank you.

Ms. ROYBAL-ALLARD. Dr. Austin, one of my legislative priorities in Congress has been newborn screening. And since its first passage in 2008, the bipartisan Newborn Screening Saves Lives Act has supported Federal programs that expand State newborn screening programs, ensures laboratory quality, and supports the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.

And the law also authorized the NICHD Hunter Kelly Newborn Screening Research Program to identify additional conditions for newborn screening and to develop and test innovative treatments. I understand that NCATS was created from several existing NIH initiatives, which included two rare disease research programs. Your mission of accelerating new treatment development is a priority that is shared by all parents of children born with the types of rare diseases that newborn screening can detect.

Given that NCATS and the Hunter Kelly Research Program have similar missions, I am interested in knowing how NCATS and Hunter Kelly work together to investigate new treatments of rare diseases that can be detected at birth and what new therapeutics are you currently investigating for diseases that could become eligible for inclusion in the recommended uniform screening panel?

Dr. AUSTIN. Mm-hmm. Wow, what a great question. I will try to be brief, although that will be difficult, given the question you asked.

The opportunity here is absolutely huge. And the way to think about this is moving, as I think I mentioned before, from the idea of studying one disease at a time to studying many diseases at a time, eventually perhaps all 7,000 at a time. And newborn screening has novel technologies, which will allow us to make that transition.

What I am talking about here is genome sequencing. About 80 percent of rare diseases are genetic, and most of them can be detected on—if we use more widespread whole genome or exome sequencing before the children leave the hospital. We are already doing this via some work we are supporting at Rady Children's

Hospital, doing genome sequencing in the NICU for particularly sick infants.

But the larger application here is to short-circuit entirely what is called the diagnostic odyssey that is this terrible wandering in the wilderness that parents do with children with rare diseases, where they will go through 5, 10, 15, 20 years of going from provider to provider to provider until one provider says, "I know what you have. I once saw one of those in medical school once." But they are so rare that they have to go to multiple providers to identify.

And most of these we could identify at birth with newborn screening across the whole genome. And so one asks, well, why aren't we doing this? So this is not so much a technical problem. There are people who are doing, supported by us and by NICHD and by the genome institute, developing and deploying these technologies, combining rapid genome sequencing, which can get done in as little as 24 hours from the time the consultation is done to when the data get back to the caring physicians and using AI to interpret the data.

So the limitation here is, as we have talked about before, is in what is called implementation science. So once the—you have proof-of-principle, and it has been—the technology has been developed and has been demonstrated as being used, how do you disseminate it to the whole community?

And this is a complex problem that, of course, includes not just research, but it includes reimbursement, et cetera. But the important lesson here is that the only reason that the odyssey exists is that Odysseus leaves home in the first place, remember? Then he has to take 10 years to get back.

If we sequenced these children before they left, we would never have that odyssey. And realize that during that 10 years, the quality and quantity of life of those children is declining, declining, declining. And by the time they are finally diagnosed, they are often beyond our ability to reach, or they have died.

And this was something when I was in training 35 years ago, we had—we knew this happened, but there was nothing we could do. This has utterly changed in the last 35 years. And so we feel a real urgency to diagnose all children who have a rare disease within a year of coming to medical attention, and many of those can be diagnosed via newborn screening.

Not all, but still, systems exist to identify them much more efficiently. This is a systems implementation science problem.

Ms. ROYBAL-ALLARD. Is there any—I am sorry—

Ms. DELAURO. No, no. Go ahead.

Ms. ROYBAL-ALLARD. I may have missed it, but is there any collaboration at all in working with the Hunter Kelly—

Dr. AUSTIN. Oh, boy. Oh, yes. We are joined at the hip with them. As a matter of fact, we hired a person who used to be at NICHD to help us run this.

We are also doing this on an international level because this is a—this is an international problem. Up until last January, I was chair of an organization called the International Rare Disease Research Consortium, and while I was chair, I am proud to say that we developed 3 new strategic goals for the next 10 years, one of which is to decrease the diagnostic odyssey from 10 to 15 years to

1 year, as well as develop in the next 10 years, 1,000 new therapies for rare diseases.

And we think that is—those therapies are only possible when you have a diagnosis. And those diagnoses also allow you to group diseases to do the therapeutic part of what we call many diseases at a time, which is to say, well, gosh, if we can target with a drug a commonality to 20 different diseases, then we have just cured 20 diseases at once, not 1. Or platform technologies like the gene therapy technologies that would be applicable to many, many diseases at a time.

And so this has diagnostic aspects and therapeutic aspects, has information aspects as well, rebuilding databases to be able to make them AI friendly, which we are doing as well.

Ms. ROYBAL-ALLARD. Thank you. I think we need to do something to help address some of those challenges that they face.

Ms. DELAURO. Actually, I am going to submit a number of question for the record, and you all have been wonderful. Just do you find that your work—I have just a couple of things, and I want to end up with one question for everything.

I guess, Dr. Brennan, the ClinicalTrials.gov, in other words, just to build on a question that Congresswoman Roybal-Allard asked, that Congresswoman Lee is talking about, is dealing with how can we bring more diversity into the clinical studies? Can you do that through your efforts?

How do we improve on ClinicalTrials.gov through—you know, to bring more people, including the underrepresented groups into it?

Dr. BRENNAN. Thank you very much for the opportunity to talk about one of our treasured resources.

ClinicalTrials.gov actually has two key purposes at NIH. One is to demonstrate stewardship of clinical trials, but the other is to let the public know about trials that are available. We have worked with the support of NIH leadership to launch an improvement of the interface for ClinicalTrials.gov so it is easier for people to find studies. We have developed better search strings so that a person who puts in a word that might be misspelled or might need to—might not be exactly the precise way that this trial is described can actually find it.

But in addition to this, we are also working with community-based groups. And in this case, the community might be breastcancer.org or special purpose communities who are able to extract from our ClinicalTrials.gov registry an entire suite of studies specific to either the neighborhoods they are working in or the populations they are working with and expose those studies through the lens of the specialty organization.

Ms. DELAURO. Thank you.

I am going to follow up with staff. This is a parochial issue on the Connecticut Medical Society and their journal being removed from Medline, but we will follow up with you on that.

Dr. BRENNAN. Thank you. We would be happy to talk about that.

Ms. DELAURO. Now I do want to do this, and I want each of you briefly to—I know it is about resources, you know? If resources were available, though, what is the innovative research that you would like to pursue?

Dr. Austin, you just mentioned a piece of this which is really quite extraordinary in a direction that we can go in. But let me just ask you, you know, where would you like to go? What would you like to pursue?

Dr. TROMBERG. You were looking at me. Does that mean I should start? [Laughter.]

Ms. DELAURO. Well, look, you know, you don't have to. This is not—it is anybody who wants to go first can go first. Let us go. You go first. [Laughter.]

Dr. TROMBERG. Okay. Well, one of the areas that I am really excited and passionate about is, is kind of the idea that current medicine, as it is practiced, takes snapshots, kind of static snapshots. A little bit of blood chemistry here. Maybe another year or two after that, an image here. Maybe another year or two or five after that, blood pressure.

You know, even that is not measured very frequently. It is difficult to measure at home. And some of you may know, every time you breathe in and out, your blood pressure changes. We call this dynamics, and the dynamics could be the most important thing about managing your blood pressure.

And then you go to the doctor's office, and your blood pressure is elevated, and they give you medication. Then you go home, and then you come back later, and they say, well, it is not working. And then you go home, and then you come back later.

So there is this iterative optimization. Current medicine is practiced at large time intervals. So a big challenge for our community is to come up with better, faster, more accurate, continuous wearable and implantable sensors that are measuring many, many complex things because we know biology is not simple. And we also know it is quite dynamic.

If we can capture the dynamics—every time you eat, your body chemistry goes crazy. How about if we could measure all those things and figure out how to better manage your diabetes and metabolic disease and prevent obesity?

What if we could wear this continuous, flexible patch that is an ultrasound device that measures blood pressure on a continuous basis? And we can look at what happens when you go to a hearing to your blood pressure. We could follow that with everyone. [Laughter.]

Dr. TROMBERG. And how well it is regulated by the medication that you are receiving from your physician. So I think this is the big challenge for us.

What it would do is it would extend health span. So it would prevent disease better. It would give people the power to control what they do and how it impacts their future health. So that is our big challenge.

Ms. DELAURO. Thank you. Thank you very much. That is a very, very interesting personal example.

My husband's doctor told him he should measure his blood pressure. So he brought this machine home. I said what are you doing, you know? I mean, and he doesn't use it, et cetera. Has no—you know, it has become just a nonfunctional piece of equipment that we now have. [Laughter.]

Dr. TROMBERG. Has he tried it with his arm up and down and his feet up and—yes.

Ms. DELAURO. In any case, that is really very, very interesting, and I was very serious about the allergy issue. It really is quite extraordinary in terms of quality of life, and I am very seriously having to look at everything that you are eating and know what you are eating and what kind of an effect that will have.

Dr. Langevin, thank you. Thank you. Where would you go?

Dr. LANGEVIN. Our innovative and kind of big idea right now is very much along the same lines that Dr. Tromberg was talking about in terms of the health span. We are very interested in health and the sort of dynamics of it.

We often think about, oh, we want to prevent disease. But one of the things we don't think about so much is how do you restore health? How do you get people back to health after they have been sick?

If you have a chronic condition, for example, that has relapses, how do you return? How do you recover? So there is all these wonderful words that start with R. You know, recovery, resilience, resistance, resolution, repair, regeneration. These are all mechanisms that we understand, we are starting to understand them now in animal models and basic biochemistry.

But how do we translate that back to the human level, and how does that relate to also what is going on psychologically? We talk about resilience, psychological resilience. But what about physical resilience, and how are the two related?

So we really want to move into that space and understand especially to utilize behavioral, physical, nutritional interventions to try to promote that and to encourage endogenous, built-in mechanisms of health that we all have inside us. But how do you boost them? How do you, you know, promote them?

Ms. DELAURO. Thank you. Dr. Brennan.

Dr. BRENNAN. The National Library of Medicine is frequently behind the scenes in every discovery that happens. One of the things we do is we make information more useful. And now with the emergence of artificial intelligence and machine learning strategies, we have the potential to take many different kinds of data types from genomic data to images, from videos of family interaction to pictures of food, and apply advanced analytics so we can more rapidly interpret what is occurring to give better and more transparent and more ethically driven recommendations about whether the food you eat is going to actually cause this metabolic storm that is being predicted.

Our work is in advancing the analytics that make information more useful to society.

Ms. DELAURO. Great. Thank you.

Dr. PEREZ-STABLE. Thank you. At NIMHD, I will mention two areas. One is know why some disadvantaged communities actually do better than predicted. So what are the protective factors that lead to this resilience? And I think one of our methods will be to leverage these data tools that are now available to link both individual factors from like the All of Us study and big data structures that exist.

And I have to mention a second one, which is related to the dire condition of the American Indian and Alaska Native population in the U.S. and looking for a special way to strengthen their own capacity to build a research capacity, engaging their communities on tribal lands, including the urban American Indians.

Ms. DELAURO. How much interaction do you have with the Indian Health Service?

Dr. PEREZ-STABLE. Well, funny you should say. Tomorrow, I am meeting with the Acting Director about a specific program, but we also have a Tribal Health Research Office. Dr. David Wilson is the Director of that, and we are in close interaction with him.

And just last Friday, I was at the Zuni Pueblo Reservation in New Mexico.

Ms. DELAURO. I know because both of those communities seem to have some very, very serious problems that we have not, you know, really focused our time and attention.

Before you answer the question, Dr. Austin, I wanted to ask does—how do you avoid duplicating your work with pharmaceutical companies. Is there—

Dr. AUSTIN. It is really there are two ways to answer that question. One is that the projects that we work on are the 95 percent of diseases and targets that can't be worked on on a return on investment environment either because the targets are too risky or not well understood enough, or the disease prevalence is too low.

So, actually, the catchment area, if you will, of the kinds of diseases that pharma can work on is actually relatively small. I learned that when I worked there before I came to the NIH.

The other is that we work on the science of drug development or the science of translation, which includes the science of drug development, but regulatory science also fits into what we call translational science. And that is a more fundamental, basic science really of how this whole process works.

That is not worked on at all by pharma and really can't be because they can't use internal drug development resources to answer fundamental science questions. So we work with them quite closely on what are the problems that they run into that kill projects, effectively, and problems that they run into.

We work with—just like we work with the FDA and other organizations on those questions. They make up about a third of our advisory board, actually, because of the Cures Acceleration Network. So we work—and we do lots of collaborations with them as well.

Ms. DELAURO. I do want us to get to a point—and I want you to answer the last question. I do want us to get to a point where there is the recognition of the amount of taxpayer dollar research is being done that then is picked up by the pharmaceutical industry.

Dr. AUSTIN. Oh, and they are very well aware of that.

Ms. DELAURO. And well, they are aware of it, but the cost of their treatment often is prohibitive to the recovery or the cure or the treatment of an individual, and where the basic research is being done at, you know, at your Institute, at the NIH, et cetera, and that needs to be figured into where we go in terms of the avail-

ability. It is great to discover it, which you do, but it is better if people can take advantage of that, of that product.

Please, where would you want to go?

Dr. AUSTIN. I would just leave you with one very provocative term, which you may not have heard before, but we are actually quite serious about, which is "just in time" gene therapy.

So wouldn't it be great if one could go from a molecular diagnosis to a kind of gene therapy which is customized to whatever the mutation is that you have in a very short period of time? And we are at the point, believe it or not, where with some kinds of gene therapy, particularly oligonucleotide-based gene therapy, which is the same sort of technology that has been used in Spinraza, if you know what that is. It is an oligo therapy for spinal muscular atrophy made by Biogen.

But the idea is that one uses essentially a molecular band-aid to put on the mutated gene to prevent it from expressing itself, and there are thousands of other diseases which are characterized by this kind of fundamental genetic lesion. And working with some researchers at Children's Hospital in Boston who have used this kind of technology in other diseases, it became evident to us is that if we could work with the FDA to figure out what are the general toxicology, manufacturing principles that the FDA needs in order to approve an IND for an individual patient then—and make all that information publicly available, then that recipe is right there.

And when a treating physician wants to treat a novel—a new person, they can go to that recipe book and pick that information up because it is in the public domain and potentially treat that child very quickly.

The other thing that I would just as far as the things that just keep me up at night because the opportunities are so huge are new uses of treatments which are already out there, and we have put a lot of effort into this area since NCATS was formed. But the fundamental idea here is that through projects like the Genome Project, we have discovered that there are not actually 7,000 individual diseases, and there aren't individual genes which function on individual cell types. They are all the same genes. They just get reproduced and reused in different ways in different diseases.

And so as a result, many of the drugs that target one could be used to target many others. But we haven't done a very good job exploiting that. We tend to say, okay, one gene—or one drug, one disease, and end it at that.

So one example that you may have heard of, because the original discovery was done at Yale, was this ketamine example, where ketamine has been around since the '50s.

Ms. DELAURO. I saw it. Saw it. Saw it used with a patient—

Dr. AUSTIN. Yes.

Ms. DELAURO [continuing]. When I was at the NIH last year.

Dr. AUSTIN. And some, some investigator, John Krystal at Yale and then Carlos Zarate and others at NIH, discovered that this was useful for suicidality and depression. The problem is it is dissociative, it is an anesthetic, it is hallucinatory, and it is an addictive. And you can only give it IV or intranasally. So it is just not a very practical treatment.

And so, working with NIMH and the National Institute on Aging, we asked, well, gosh, if it isn't actually ketamine doing it, is there an active molecule in the body that is actually doing the anti-depressive activity that wouldn't have all the other stuff—wouldn't be addictive, wouldn't be dissociative, wouldn't be sedating, all of that stuff. And so doing some very fancy chemistry, we figured out what that molecule is.

It is actually a byproduct that your body makes when a person take ketamine. It also happens to be orally available. And so working again with our colleagues—this was a big team effort and continues to be, we are working through the drug development process now to do all the manufacturing and safety and toxicology and all that to get into people.

And what is so exciting is that this has a completely different mechanism of action than ketamine was thought to have. So it has illuminated novel concepts in mental health and potentially will give us treatments not only for depression, but potentially there is evidence for anxiety, obsessive-compulsive disorder, pain, and PTSD.

And so we will be doing trials in all of those at the Clinical Center probably starting next year.

Ms. DELAURO. Dr. Collins, do you just want to just wrap up from your point of view? And then I will—

Dr. COLLINS. Do I get one also about what is like really an idea that hasn't been—

[Laughter.]

Ms. DELAURO. Yes, you do. Yes, you do.

Dr. COLLINS [continuing]. Hasn't been brought up yet.

Ms. DELAURO. Sure.

Dr. COLLINS. And that is the brain. We haven't had a chance in this conversation, because we had so many things to talk about, to highlight the remarkable journey we are in the middle of, trying to figure out by developing new technologies—and there is a lot of them that are pretty exciting—how those 86 billion neurons between your ears do what they do.

And how to use that information then to understand how to prevent and treat schizophrenia, Alzheimer's disease, Parkinson's, autism, depression, epilepsy, on down that long list. We are now 5 years into the BRAIN Initiative, which you all have supported with appropriation, and we will release in the very near future an entirely new plan for the next 5 years, which is enough to knock your socks off in terms of what the capabilities now are for beginning to take apart how these circuits in the brain actually do what they do.

When history looks back at this era in biomedical research, they will probably point to a lot of things. They will definitely point to this as crossing into new territory where we really began to understand the most complicated structure in the known universe, the human brain.

Ms. DELAURO. Extraordinary, and I mean that just broadly speaking in terms of the information this morning. That is why I was so anxious, you know? It is very special to hear from each and every Director, Centers to find out what you are doing so that we

can be responsible in the role that we play in fostering what you do.

You know, all of our kids have the expression, the testimony this morning, it is awesome. It is really that is all of our—you know, you can go to any—but more than that, we have the ability, which we try to do, to provide the resources in order for you to carry out what you do. They are not unlimited, as you know, but we try our best to continue the effort.

I would ask you to pursue, as you do, the science of what you do. None of us here are scientists. We are not. We are not doctors. And we have got to take our lead from you. We cannot just pick and choose where we think dollars should go, but we need to—and we do have the faith and trust in you to follow the science and have the money and the resources help you to follow that science for the discovery.

An area that you—and I ask you as well, Dr. Austin, when you talk about gene therapy and genetics, we cannot allow people's personal theology or beliefs to direct where our scientific discovery and those dollars go. You are a bulwark against that.

It is oftentimes uncomfortable to enter that arena because that is not what your training and your professional ability direct you. But you have such standing, domestically and internationally, to guide us through with the safeguards. You understand better than anyone what those safeguards need to be and what the ethics need to be.

But we cannot at the Federal level be in the business of shutting down biomedical research. It is not what we came here to do. You know, always, as I say, you know—and we will, again, cooperate with you. Your testimony this morning, the work that you do helps us to do our job better. I can only hope that what we do helps you to do your job better.

Thank you for being here this morning. The hearing is adjourned.

[Material submitted for inclusion in the record follows:]

Committee on Appropriations
Labor, Health & Human Services, and Education Subcommittee
*Investments in Medical Research at Five Institutes and Centers of
the National Institutes of Health (9.25.19)*

Questions for the Record for Dr. Austin

Submitted by Congresswoman DeLauro

NCATS Role in Drug Development for Rare Diseases

I understand that NCATS is applying translational research to accelerate the development of treatments for rare diseases.

Question:

1. How does NCATS accomplish this and how does it avoid duplicating the work of private pharmaceutical companies?

Response: With approximately 7,000 different rare diseases affecting an estimated 25-30 million Americans, rare diseases are cumulatively more common and complex than the name “rare diseases” would imply. NCATS’ “many diseases at a time” strategy is a long-term effort to transform the understanding, diagnosis, and treatment of rare diseases by focusing on what is common to diseases rather than what is different, with goals in awareness, information, diagnosis, and treatment.

Awareness goal focuses on the idea that rare diseases are not rare, but rather cumulatively affect 8 percent of the American population – over 25 million people, about the same number as have diabetes.

Information sharing goal focuses on a completely revamped Genetic and Rare Diseases, or GARD, database, which provides information to patients and parents about rare diseases and how they relate to each other.

Diagnosis goal is to reduce the time it takes for someone with a rare disease to be accurately diagnosed from its current 10 years to less than a year.

Treatment goal is to develop therapies that can treat multiple diseases by focusing on commonalities among rare diseases and platform technologies to treat them. Each of these is entirely feasible, albeit technologically challenging – and each has enormous potential to transform the lives of patients.

NCATS has many initiatives that focus on rare diseases, including utilizing its Cures Acceleration Network (CAN) to advance the development of high-need cures and reduce significant barriers between research discovery and clinical trials. CAN provides the opportunity to conduct high-risk/high-reward research to test innovative approaches to translational science. One current initiative is the PaVe-GT (Platform Vector Gene Therapy) pilot program. Gene therapy offers tremendous promise, particularly for rare genetic diseases and some cancers; however, current technologies for gene therapy delivery have limitations. NCATS is exploring new strategies to speed gene therapy by developing standardized delivery vehicles so scientists can focus on what is being delivered rather than how to deliver it. This platform approach could get highly effective treatments to patients faster and make the process more efficient. The goal of

the PaVe-GT is to streamline and accelerate the development of gene therapies for rare diseases by moving from the current “one disease at a time” to a “many diseases at a time” approach.

NCATS’ work to accelerate development of treatments for rare diseases is by design enabling of, and complementary to, the work of private pharmaceutical companies, in three ways. First and most importantly, NCATS’ mission to advance the *science* of translation is entirely different from and complementary to the product development missions of pharmaceutical companies. Like any other science, advances in translational science will enable the work of those companies, but fundamental translational science is not their mission, since the “product” of that science is enabling knowledge, not a saleable product. Secondly, NCATS’ work is enabling and complementary in that the Center works on the 95 percent of rare diseases (~6,000 individual diseases) that are so uncommon and poorly understood as to be too risky for a company to work on while meeting their fiduciary obligations; looked at it this way, NCATS’ role is to “de-risk” these projects by providing data and/or proof-of-principle treatments sufficient to enable a company to work on that disease for the first time. And thirdly, since translation is a *process*, not an *event* – one which requires over 10 years from start to finish – NCATS works on the first half of this process, enabling the companies to complete the other half and get a product to market within the roughly 5-year window generally required in a return-on-investment environment of a company.

In 2019 alone, NCATS has collaborated with academic and biopharmaceutical company partners in the filing of eight Investigational New Drug (IND) applications with the FDA, a record of achievement that dramatically illustrates the effectiveness and impact of the NCATS model. Each of these projects has or will typically transition to a biopharmaceutical company for completion of development.

The Future of CTSA's

I am personally very interested in the work of NCATS because it is essential to realizing the promise of the outstanding research conducted at universities, research hospitals, and of course NIH's own laboratories. High quality translational science is essential for bringing potential therapies to patients. The Clinical Translational Science Awards program has proven itself as a strategy for building our national capacity in translational science, and I hope it will remain a high priority for NCATS.

Question:

1. Would you discuss your vision for the future of the program, especially in light of the call for comments on the program that you issued earlier this month?

Response:

NCATS' flagship Clinical and Translational Science Awards (CTSA) Program comprises a dynamic suite of initiatives focused on fostering and improving clinical and translational research and science. The Program supports a nationwide network of institutions capable of addressing important roadblocks in clinical translation by working together locally, regionally, and nationally and will always be a high priority for NCATS. CTSA Program support enables research teams to tackle system-wide scientific and operational problems in clinical and translational research that no one team can overcome. Some of the biggest translational roadblocks are in the clinical domain, such as clinical trial recruitment, Institutional Review Board (IRB) review processes, use of the Electronic Medical Records (EMR) in research, innovative clinical trial designs, and clinical outcome measures. The CTSA Program works to

understand and develop solutions for these complex scientific needs. The Program's present focus areas include—

- Harnessing informatics, telemedicine, and mobile technologies
- Increasing the quality and efficiency of clinical trials
- Leveraging the potential of community engagement to enhance clinical research
- Integrating special and underserved populations in translational research across the lifespan
- Training and cultivating the translational science workforce.

NCATS is embarking on a deliberative information gathering process that will inform changes to the CTSA Program to meet its broad scientific mission to improve the efficiency and effectiveness of clinical research and translational science. The Center is seeking broad input from stakeholder communities, including through a Request for Information (RFI)¹ issued in September 2019 and through a “town hall” to be held in early 2020. The RFI requested input on how the CTSA Program might be strengthened to deliver on its promise to develop, demonstrate, and disseminate innovative approaches, methodologies, and interventions that translate into improved human health. NCATS is seeking input on the program's objectives, operations and outcomes, including those that may merit increased emphasis, those that may no longer be needed and those that the program is not currently addressing but should. NCATS also is interested in ideas for measuring the impact of the program. NCATS is collecting suggestions from existing CTSA Program grantees, as well as from other academic, regulatory, industry, and patient organizations. Prior to implementation, NCATS will share any planned updates to the CTSA Program with the Committee.

¹ <https://grants.nih.gov/grants/guide/notice-files/NOT-TR-19-027.html>

Committee on Appropriations
Labor, Health & Human Services, and Education Subcommittee
*Investments in Medical Research at Five Institutes and Centers of
the National Institutes of Health (9.25.19)*

Questions for the Record

Submitted by Congresswoman Lee

Maternal Health

Question: Dr. Collins, how is the NIH is coordinating their efforts on maternal mortality with other federal agencies like the CDC and HRSA? How are you specifically working on black maternal health?

Is the NIH specifically focusing on racial and ethnic disparities in maternal mortality and severe morbidity rates?

Response: Maternal mortality and severe maternal morbidity are a major priority for the Department of Health and Human Services. The National Institutes of Health (NIH), including the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the NIH Office of Research on Women's Health, are fully participating in the trans-HHS efforts on maternal mortality and morbidity, including the HHS Working Group on Maternal Mortality. Members of this working group include the Centers for Disease Control and Prevention, the Health Research and Services Administration, and the Indian Health Service, among others.

Through a wide range of investigator-initiated grants and contracts, NIH research on maternal mortality and severe maternal morbidity is aimed at identifying and addressing the biomedical causes and understanding the social and behavioral contexts that can lead to these conditions. To better track spending on this critically important public health issue, NIH created an official

reporting category in 2017 for maternal health, which includes both maternal morbidity and death.¹ This new resource demonstrates the significant investments that NIH is making to address knowledge gaps in risk prediction, severe morbidity, optimal timing for delivery, maternal long-term outcomes, and data collection. The total spending for maternal health in 2018 was \$303 million.²

Even with these existing research efforts, NIH acknowledges that far more work is needed to reduce maternal morbidity and mortality rates in the United States, especially among black women. For research directly related to pregnancy, NIH spent \$419 million in 2018.² NICHD leads the NIH's research on pregnancy; the leading causes of maternal morbidity and mortality are a priority, as delineated in the Institute's new strategic plan³. Currently funded studies address causes of maternal mortality at different points during pregnancy, such as infection, amniotic fluid embolism, hemorrhage, and cardiovascular conditions. For example, an NICHD-supported study found that pretreating women with an antibiotic before delivery lowered rates of infection after cesarean delivery.⁴ NICHD researchers are also investigating treatments to reduce death attributed to hemorrhage that have worked in low-to-middle income countries.⁵ In addition, NICHD supports research on high risk pregnancies at its intramural research branch in Detroit, Michigan.

Other NIH Institutes and Centers (ICs) also support research to better understand conditions that occur in pregnancy. Some examples include preeclampsia (National Heart, Lung, and Blood Institute), gestational diabetes (National Institute of Diabetes and Digestive and Kidney Diseases), and postpartum depression (National Institute of Mental Health). With these other ICs, NICHD is working to develop a research agenda. In 2019, the NICHD led two national meetings to gather information on the contexts of maternal mortality. The first meeting⁶ brought together representatives from community-based and professional health groups to discuss what is

¹ https://report.nih.gov/categorical_spending.aspx

² https://report.nih.gov/categorical_spending.aspx

³ https://www.nichd.nih.gov/sites/default/files/2019-09/NICHD_Strategic_Plan.pdf

⁴ <https://doi.org/10.1056/NEJMoa1602044>

⁵ <https://doi.org/10.1016/j.ajog.2019.05.050>

⁶ <https://videocast.nih.gov/summary.asp?Live=31665&bhcp=1>

needed to help improve maternal health. The second meeting⁷ focused on the research needed to reverse the increasing rates of both maternal mortality and severe maternal morbidity. Much of the discussion centered on health disparities and how to reach populations that are disproportionately affected. The third meeting, planned for spring 2020, will develop a research agenda to address the clinical causes and co-occurring conditions that increase the risk of morbidity and mortality. Experts will present information about why women die from these conditions and the research gaps that need to be addressed to reduce maternal morbidity and mortality in the United States. In the meantime, NICHD is also supporting a study⁸ conducted by the National Academy of Sciences to examine the impact of different birth settings on maternal mortality and morbidity and social determinants that influence risk and outcomes.

In addition, NICHD conducts several activities to address maternal health during pregnancy. These efforts may be used to inform research on maternal morbidity and mortality. They include:

- The Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) submitted a report⁹ to the Secretary of Health and Human Services in 2018 with recommendations about how to improve gaps in knowledge and research on safe and effective therapies for pregnant women and lactating women. Phase II of the Task Force is expected to issue a plan on how to implement those recommendations in 2020.
- The Human Placenta Project (HPP)¹⁰ is a collaborative research effort that aims to develop new tools to study the placenta in real time to learn how it develops and functions.

⁷ <https://videocast.nih.gov/summary.asp?Live=31709&bhcp=1>

⁸ <https://www8.nationalacademies.org/pa/projectview.aspx?key=51457>

⁹ https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf

¹⁰ <https://www.nichd.nih.gov/research/supported/HPP/default>

- PregSource®¹¹ is a crowdsourcing research project that will help researchers learn how women from a variety of backgrounds experience pregnancy, which may lead to improvements in care.

HIV/AIDS

Question: Dr. Collins, could you tell the committee that if that money were to be included in the final FY 20 bill – what would that mean for ending HIV? How would the NIH exactly use that money and where would it be targeted?

Response: The NIH HIV/AIDS Research Program and NIH Strategic Plan for HIV and HIV-Related Research (The Plan), identifies research priorities for NIH-funded intramural and extramural research. The Plan informs the general public, scientific community, Congress and policy-makers, and communities affected by HIV about the NIH HIV research agenda. The strategic goals of the Plan closely align with the goals of the current National HIV/AIDS Strategy for the United States (NHAS): Updated to 2020¹² and the domestic President’s Emergency Plan for AIDS Relief (PEPFAR), which is the basis of the NHAS, to ensure that the NIH HIV/AIDS research agenda is moving in a concerted, national direction. Allocation of additional funds would expand the research objectives and goals, particularly to enhance the synergy between the NIH HIV/AIDS agenda and NHAS.

Question: What’s the long-term funding – and support -- needed to meet the Initiative’s stated goal of reducing HIV infections by 75% in the next five years and by 90% in the next 10 years?

Response: The Ending the HIV Epidemic Initiative is an HHS-wide effort over the next decade to reach these ambitious but achievable goals in the United States. NIH-funded research has supported development of the science and tools that make the ambitious goals of this initiative possible. NIH would inform HHS partners on best practices, based on state-of-the-art biomedical

¹¹ <https://www.nichd.nih.gov/research/supported/pregsource>

¹² <https://www.hiv.gov/federal-response/national-hiv-aids-strategy/nhas-update>

research findings, and by collecting data on the effectiveness of approaches used in this initiative.

Research Endowment Program

Question: Dr. Perez-Stable - In 2018 your scientific advisory council provided recommendations on reinvigorating the Research Endowment Program. Can you please tell the committee how the NIMHD is responding to the recommendations of the scientific advisory council?

The original purpose of the endowment program is help minority serving research institutions reach the median of endowments of similar health professions institutions. Have any of the institutions reached that goal?

When is the next expected funding opportunity announcement (FOA) for the Research Endowment Program?

Response: The Research Endowment Program (REP) provides funds to under-resourced academic institutions with a diverse student body and faculty, to support endowments that will help to increase research capacity and training to promote minority health and health disparities research. The research at these institutions focuses on a range of topics including social determinants of health, environmental health disparities, men's health, precision medicine, chronic disease prevention, and health services and policy research. In 2017, National Institute of Minority Health and Health Disparities (NIMHD) created a workgroup of Advisory Council members, external scientific experts, and NIMHD staff to review the REP. NIMHD has embraced the recommendations from the workgroup, including eliminating any time limit on having a REP award. They will be incorporated, where possible, into the next funding opportunity announcement for the REP that will be published in FY2020. While the REP has significantly enhanced the endowment of participating institutions, no institution has reached the median endowment level.

Committee on Appropriations
Labor, Health & Human Services, and Education Subcommittee
Investments in Medical Research at Five Institutes and Centers of the
National Institutes of Health (9.25.19)

Questions for the Record for Dr. Collins

Submitted by Congresswoman Roybal-Allard

Newborn Screening Dried Blood Spots and the HHS “Common Rule”

Newborn screening is one of our nation’s greatest public health success stories, saving or improving the lives of hundreds of thousands of children since population screening began almost 60 years ago. In that time, we have progressed from screening for just one disorder, phenylketonuria, to screening for 35 federally recommended conditions that would lead to disability or death in affected children if not for newborn screening.

The rapid expansion of newborn screening is due, in part, to pioneering research at the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) to discover treatments for heritable conditions and develop new screening technologies. Much of this research relies on residual dried blood spots stored by some state newborn screening programs.

The Newborn Screening Saves Lives Reauthorization Act of 2014 (P.L. 113-240) included a provision (Section 12) that required informed consent in order to use nonidentified residual dried bloods in federally funded research. This restriction was in effect for any new blood spots collected from 90 days following the Act’s enactment to such time as the Department of Health and Human Services promulgated its final revised Federal Policy for the Protection of Human Subjects (the Revised Common Rule).

The requirements of Section 12 have now sunset as the Revised Common Rule became effective on July 19, 2018. During the revision process for the Common Rule, HHS explicitly considered whether studies using non-identified biospecimens, including residual dried blood spots, should be subject to the same protections as research involving human subjects. After careful review of the issue and considering stakeholder feedback received through the public comment process, HHS determined that research using non-identified biospecimens, including residual dried blood spots, would be considered secondary research and not subject to the Revised Common Rule.

Questions:

1. How are residual dried blood spots used to improve newborn screening and what makes them an invaluable resource to researchers?
2. Can you describe the impact of Section 12 on NIH's newborn screening research during the time it was in effect?
3. If Congress were to impose similar and permanent restrictions on the use of nonidentified dried bloods spots in federally funded research, what would be the impact on the development of future newborn screening diagnostic tests and treatments?
4. How would such a permanent restriction hinder the expansion of our nation's newborn screening system?

Response:

Newborn screening is a public health success story - since newborn screening programs began in the 1960s, more than 150 million infants have been screened for genetic and congenital disorders, preventing disease and disability. When the program first started, screening was performed for only a single disorder, phenylketonuria (PKU). Changing the diet of infants diagnosed with PKU has significantly reduced the intellectual disabilities that would otherwise result if the condition

remained undiagnosed. Currently, the HHS Secretary's Advisory Committee on Heritable Disorders recommends that every state's newborn screening program include the diagnostic tests for 35 core disorders and 26 secondary disorders listed on the recommended uniform screening panel (RUSP). Babies are screened for genetic conditions in all 50 states, although the specific panel of tests varies state-to-state. The nationwide newborn screening program allows families to avoid the diagnostic journey that can sometimes take years before a condition is definitively diagnosed and treatment can be obtained. In addition, in most cases, earlier treatment can prevent or ameliorate the most serious health effects.

Through its Hunter Kelly Newborn Screening Research program, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) supports research on newborn screening to improve existing screening techniques or develop new ones; expands the number of conditions for which screening tests are available; and develops new treatments and disease management strategies for conditions that can be detected. A large portion of this research relies on residual, "deidentified" (anonymized) dried blood spots stored by state newborn screening programs. Without this source of research specimens, effectively developing and validating new genetic screening tests for inclusion on the RUSP is challenging.

The Newborn Screening Saves Lives Reauthorization Act of 2014 (P.L. 113-240) included a provision that required informed consent before even deidentified dried blood spots could be used in federally funded research. This restriction was in effect for any new blood spots collected from 90 days following enactment until HHS announced its final revised Federal Policy for the Protection of Human Subjects (the revised Common Rule). During the revision process for the Common Rule, HHS explicitly considered whether studies using deidentified biospecimens, including residual dried blood spots, should be subject to the same protections as research involving human subjects. While the Act's consent provision was in effect, it resulted in critical delays in research, including hindering or preventing the development of new laboratory tests, improving existing laboratory tests, and implementing new tests in a timely manner, even in initiating pilot studies for conditions that had recently been added to the RUSP (e.g., Pompe disease).

For example, NICHD had announced support for studies to provide the evidence base to inform additional nominations for new conditions to be added to the RUSP, including mucopolysaccharidosis and spinal muscular atrophy. This is important, as new treatments for spinal muscular atrophy are available and prevent severe morbidity and early mortality. However, the states that NICHD had engaged to conduct the pilot studies were unwilling to initiate such studies because they believed they could not perform pilots for additional conditions without obtaining informed consent, which was logistically and fiscally difficult. Consequently, during the period in which the informed consent provision was in effect, NICHD was only able to engage in implementation studies on tests already on the RUSP, rather than providing key clinical data prior to a condition's nomination and addition.

After careful review of the issue and considering stakeholder feedback received through the public comment process, HHS determined that research using deidentified biospecimens, including residual dried blood spots, would be considered secondary research and not subject to the revised Common Rule. The revised Common Rule was announced in 2018 and implemented in January 2019. Currently, NICHD is planning a new pilot study for a condition that has great potential to be added to the RUSP (urea cycle defects). To again require consent for deidentified blood spots to be used in research could impede this study, along with many others in the future.

All of Us Initiative and Pediatric Inclusion

In December 2017, the Child Enrollment Scientific Vision Working Group to the All of Us Research Program Advisory Panel released its final report. The report identified the major themes and opportunities presented by the inclusion of children in the All of Us Research Program cohort study and validated earlier recommendations that children be included in All of Us.

Question: Could you please provide an update on the progress the All of Us Research Program has made to date in enrolling children and supply a timeline for future action?

Response: The enrollment of children in the *All of Us* Research Program is a priority. In order to do this responsibly there are important considerations including ensuring compliance with state legal requirements, having the appropriate consent and assent procedures required for children to join the study, enabling variable data collection methods across the childhood lifespan, considering the challenges of returning information, and managing different communications and informational needs for child participants and their guardians at each developmental stage. *All of Us* is working to address all of these considerations before beginning to enroll children. Furthermore, the Program is cognizant of the need to maximize the long-term scientific utility of the pediatric data collected, ensuring that data from the pediatric protocol has the power to advance precision medicine research for participants who continue in the program as adults.

All of Us continues to evaluate all elements within the initial adult research protocol that need to be modified to enroll children into the program. The Child Enrollment Scientific Vision Working Group (CESVWG), an expert working group of the *All of Us* Research Program Advisory Panel, first convened in the summer of 2017 and completed its work in early FY 2018. The final report of the working group, posted publicly on January 18, 2018, describes certain types of research that *All of Us* may be uniquely positioned to enable through the enrollment of children.¹

Since the release of the CESVWG report, *All of Us* assembled two task forces from members of its Special Populations Committee: The Pediatric Operational Task Force (POTF) and the Pediatric Scientific Vision Task Force (PSVTF). The POTF has started to work through all components of the program (engagement, consent, assessments, return of information, etc.) to identify necessary updates to the study's protocol to enable enrolling children. The PSVTF has refined the pediatric scientific research objectives included within the CESVWG report. The work of these task forces and the experts that serve on them is vital to the realization of pediatric enrollment. With their input, *All of Us* is developing and will implement plans to enroll children that reflect the broad and rich diversity of the U.S. population, with additional emphasis on those historically under-represented in biomedical research. Their work will be invaluable to finding scientific solutions that align with the program's objectives and core values.

¹ allofus.nih.gov/sites/default/files/cesvwg_1-18-18.pdf

Of note, the Program is collecting information related to childhood through collection of adult individuals' Electronic Health Records. This information from those enrolled over the age of 18 years is part of their EHRs and can provide an early window into childhood health while the Program continues to work on directly enrolling children.

Additionally, the Program recently partnered with the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) on a pilot to refer *All of Us* participants who are or become pregnant to PregSource, which is a study that collects information from pregnant women throughout the course of their pregnancy.² *All of Us* and NICHD are excited to have launched the pilot at the end of October 2019. The goal of the pilot is to give us a start on capturing pregnancy information and allow us to gauge *All of Us* participant interest in joining other independent research programs such as PregSource.

Enrolling children into the cohort is critically important and *All of Us* appreciates the excitement from the pediatric research community. This remains a priority. The Program's careful approach will enable a wide range of important precision medicine discoveries to improve children's health while also being mindful of the sensitivities and protections required to include minors.

Workplace Violence, Suicide and the Nursing Profession

The health care and social service industries experience the highest rates of injuries caused by workplace violence. Nurses, social workers, psychiatric, home health, and personal care aides are all at increased risk for injury caused by workplace violence. The Bureau of Labor Statistics reported that in 2017, rates of violence and injury caused by persons in these workplaces ranged from 3 times to as high as 61.9 times the average American workplace.

² pregsource.nih.gov/

Additionally, a 2019 UCSD national investigation showed that there are significantly higher rates of suicide among both male and female nurses compared to the general population.

Question: Given these concerning statistics, is NIH currently engaged in any research to look at how the workplace environment affects the physical and mental health of nurses?

Response: The NIH recognizes the Committee’s concern regarding workplace violence and its effects on the nursing workforce. While this area of research is beyond the scope of NIH’s mission, several other federal agencies do cover this important topic and offer initiatives and resources to understand and prevent violence in the healthcare workplace.

For example, CDC’s National Institute of Occupational Health and Safety supports, conducts, and publishes research on risk factors and prevention of workplace violence, and provides information and resources intended for employers and healthcare professionals, including nurses. Other agencies, including the Department of Labor’s Occupational Safety and Health Administration, and HHS’s Office of the Assistant Secretary for Preparedness and Response, offer resources that address workplace violence in healthcare settings.

Research in Women and Pregnancy

As you know, there are conditions and diseases that are specific to women – like pregnancy and preeclampsia, but there are also diseases that present differently in women than in men – like cardiac disease. With the rising rates of maternal mortality in this country, and widening health disparities among women of reproductive age, we still don’t know enough about women’s health during pregnancy, and there continues to be a lack of prioritization and knowledge gap related to research in pregnant women. But there also seems to be a gap when it comes to investment in research to address the underlying causes of health disparities in women.

Question: How much federal funding is invested at the NIH on research in health conditions specific to women or in conditions that present differently in women?

Response:**Total Investment in Women’s Health-Related Research, FY 2008 – FY 2018**

In 2018, NIH’s total investment in women’s health was over \$5 billion.

Table 1 shows the annual dollar amount invested in women’s health-related research from FY 2008 to FY 2018 according to funding statistics documented annually by the NIH Research, Condition, and Disease Categorization (RCDC) system. The Institute with the highest dollar amount is the National Cancer Institute (NCI). The Institutes with the next four highest overall investments during this time period are: the National Heart, Lung, and Blood Institute (NHLBI); the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK); the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD); and the National Institute on Aging (NIA).

Research Investment in Diseases and Conditions Specific to or Predominantly Affecting Women, FY 2008 – FY 2018

Table 2 shows total annual investments tracked in the official NIH RCDC system for diseases and conditions specific to or predominantly affecting women, by year from FY 2008 to FY 2018. Diseases and conditions specific to women are displayed in the top 11 rows, and those that predominantly affect women but also affect men to a lesser extent are identified in the bottom 13 rows.

For each of the diseases and conditions listed in Table 2, Table 3 shows the top five NIH Institutes and Centers (ICs) in terms of the amount invested in these diseases and conditions specific to or predominately affecting women (FY 2016 – FY 2018). The highest-investing IC is given in the ‘1st’ column of Table 3, with the next four ICs listed in descending order. IC rankings for all but three of the diseases and conditions are based on average funding from FY 2016 to FY 2018. The rankings for (i)

Breastfeeding, Lactation, and Breastmilk; (ii) Maternal Health; and (iii) Pregnancy are based on funding from FY 2017 to FY 2018, because these three categories were newly added in FY 2017.

Table 1: NIH total investment in Women's Health-Related Research (1), FY 2008 – FY 2018

Fiscal Year	Total NIH investment tracked by RCDC Women's Health Research category (dollars in millions)	Top five Institutes/Centers funding support levels in RCDC Women's Health Research category (in descending order)
2008	\$3,514	NCI, NIDDK, NHLBI, NICHD, NINDS
2009(2)	\$3,725	NCI, NIDDK, NHLBI, NICHD, NIDA
2010(2)	\$3,691	NCI, NICHD, NHLBI, NIDDK, NIDA
2011	\$3,891	NCI, NHLBI, NICHD, NIDDK, NIA
2012	\$3,833	NCI, NHLBI, NICHD, NIDDK, NIA
2013	\$3,745	NCI, NHLBI, NIDDK, NICHD, NIA
2014	\$3,935	NCI, NHLBI, NIDDK, NICHD, NIA
2015	\$3,989	NCI, NHLBI, NIA, NIDDK, NICHD
2016	\$4,540	NCI, NIA, NHLBI, NIDDK, NICHD
2017	\$4,769	NCI, NIA, NHLBI, NIDDK, NICHD
2018	\$5,048	NCI, NIA, NHLBI, NIDDK, NICHD

Data Source: NIH RCDC Budget Estimating Tool (RBET) Data Repository.

- (1) Includes diseases that are specific to or that predominately affect women, as well as conditions that have an impact on both sexes, however, with a specific focus on the female population.
- (2) The reported amount excludes American Recovery and Reinvestment Act (ARRA) funds. ARRA associated women's health research spending was \$506 million in FY 2009 and \$449 million in FY 2010, respectively.

Table 2: NIH total investments from RCDC tracked diseases and conditions specific to women or predominately affecting women
(in millions of dollars): FY 2008 – FY 2018⁽¹⁾

Disease Category	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2008-2018 Total ⁽⁵⁾
Diseases and conditions specific to women												
Breast Cancer	\$726	\$722	\$763	\$715	\$800	\$657	\$682	\$674	\$656	\$689	\$721	\$7,805
Ovarian Cancer	\$96	\$102	\$122	\$138	\$147	\$133	\$131	\$118	\$144	\$151	\$159	\$1,441
Cervical Cancer	\$69	\$84	\$93	\$119	\$112	\$98	\$116	\$99	\$99	\$114	\$112	\$1,115
Maternal Health ⁽³⁾	--	--	--	--	--	--	--	--	--	\$249	\$303	\$552
Uterine Cancer	\$16	\$25	\$26	\$40	\$42	\$39	\$52	\$57	\$50	\$45	\$47	\$439
Violence Against Women	\$45	\$39	\$36	\$34	\$36	\$31	\$35	\$31	\$30	\$30	\$32	\$379
Fibroid Tumors (Uterine)	\$16	\$18	\$12	\$14	\$10	\$9	\$10	\$12	\$12	\$11	\$13	\$137
Endometriosis	\$15	\$15	\$15	\$14	\$9	\$7	\$7	\$10	\$10	\$6	\$7	\$115
Vaginal Cancer	--	--	--	--	\$8	\$7	\$7	\$6	\$5	\$5	\$12	\$50
Pelvic Inflammatory Disease	\$3	\$3	\$4	\$4	\$3	\$3	\$2	\$4	\$3	\$2	\$7	\$38
Vulvodynia	--	\$1	\$2	\$2	\$4	\$4	\$3	\$2	\$2	\$1	\$2	\$23
Diseases and conditions predominately affect women ⁽²⁾												
Breastfeeding, Lactation and Breast Milk ⁽³⁾	--	--	--	--	--	--	--	--	--	\$92	\$77	\$169
Pregnancy ⁽³⁾	--	--	--	--	--	--	--	--	--	\$319	\$419	\$738
Teenage Pregnancy	\$21	\$23	\$22	\$19	\$18	\$17	\$16	\$14	\$14	\$14	\$17	\$195
Estrogen	\$245	\$235	\$231	\$227	\$221	\$218	\$203	\$194	\$205	\$220	\$230	\$2,429
Rett Syndrome	\$9	\$9	\$13	\$12	\$13	\$13	\$12	\$12	\$14	\$15	\$16	\$138
Interstitial Cystitis	\$10	\$11	\$12	\$13	\$10	\$10	\$9	\$10	\$9	\$10	\$13	\$117
Lupus	\$126	\$115	\$112	\$106	\$108	\$92	\$99	\$90	\$97	\$109	\$123	\$1,177
Osteoporosis	\$183	\$198	\$181	\$179	\$181	\$164	\$141	\$146	\$141	\$139	\$152	\$1,805
Scleroderma	\$20	\$21	\$19	\$25	\$24	\$21	\$24	\$22	\$18	\$17	\$23	\$234
Chronic Fatigue Syndrome (ME/CFS)	\$4	\$5	\$6	\$6	\$5	\$5	\$5	\$6	\$8	\$15	\$14	\$79
Rheumatoid Arthritis ⁽⁴⁾	--	--	--	--	--	--	--	--	\$59	\$91	\$93	\$335
Fibromyalgia	\$12	\$11	\$9	\$11	\$13	\$11	\$10	\$8	\$11	\$14	\$14	\$124
HPV and/or Cervical Cancer Vaccines	\$19	\$25	\$25	\$24	\$26	\$25	\$38	\$31	\$38	\$59	\$37	\$347

Data Source: RePORT - Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC) summary table at https://report.nih.gov/categorical_spending.aspx.

- (1) The research categories are not mutually exclusive. Individual projects can be included in multiple categories. Therefore, amounts presented within each column do not add up to 100% of NIH-funded research.
- (2) Rankings of diseases/conditions that predominately affect women based on scientific relevance and disease prevalence, in descending order.
- (3) RCDC categories introduced in FY 2017.

- (4) RCDC category introduced in FY 2015.
- (5) Amount not adjusted for cumulative effect of inflation from FY 2008 through FY 2018.

Table 3: Top five NIH Institutes and Centers in terms of amount invested in diseases and conditions specific to or predominately affecting women, in descending order⁽¹⁾

Disease Category	1st	2nd	3rd	4th	5th
Diseases and conditions specific to women					
Breast Cancer	NCI	NIEHS	NIGMS	NIBIB	NIMHD
Ovarian Cancer	NCI	NIGMS	NCATS	NIBIB	NHGRI
Cervical Cancer	NCI	NIAID	NICHD	NIMHD	NIBIB
Maternal Health ⁽¹⁾	NICHD	NHLBI	NIMH	NIAID	NIEHS
Uterine Cancer	NCI	NHGRI	NIEHS	NICHD	NIGMS
Violence Against Women	NICHD	NIAAA	NIDA	NIMH	OD
Fibroid Tumors (Uterine)	NIEHS	NICHD	NIMHD	NCCIH	NCI
Endometriosis	NICHD	NIEHS	NCCIH	NCI	NINDS
Vaginal Cancer	NCI	NIAID	NICHD	FIC	⁽³⁾
Pelvic Inflammatory Disease	NIAID	NINR	NICHD	NIGMS	OD
Vulvodynia	NICHD	NIDDK	NIGMS	NIAID	⁽³⁾
Diseases and conditions predominately affect women ⁽²⁾					
Breastfeeding, Lactation and Breast Milk ⁽¹⁾	NICHD	NIDDK	NIAID	NIEHS	OD
Pregnancy ⁽¹⁾	NICHD	OD	NIEHS	NHLBI	NIAID
Teenage Pregnancy	NICHD	NIDA	NINR	NIGMS	NIMH
Estrogen	NCI	NIEHS	NIA	NICHD	NHLBI
Rett Syndrome	NINDS	NIMH	NICHD	NCATS	NHLBI
Interstitial Cystitis	NIDDK	NIA	OD	NCI	NCCIH
Lupus	NIAMS	NIAID	NHLBI	NIEHS	NIGMS
Osteoporosis	NIAMS	NIA	NHGRI	NIDDK	NIDCR
Scleroderma	NIAMS	NHLBI	NHGRI	NIAID	NEI
Chronic Fatigue Syndrome (ME/CFS)	NIAID	NINDS	OD	NINR	NHLBI
Rheumatoid Arthritis	NIAMS	NHGRI	NIAID	NHLBI	NIGMS
Fibromyalgia	NIAMS	NCCIH	NINDS	NIDA	NINR
HPV and/or Cervical Cancer Vaccines	NCI	NIAID	NIMHD	NICHD	NIGMS

Data Source: RePORT- Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC) summary table at https://report.nih.gov/categorical_spending.aspx.

- (1) Institute and Center rankings for disease categories are based on average funding from FY 2016 – FY 2018, except for Breastfeeding, Lactation and Breastmilk; Maternal Health; and Pregnancy, which were new categories in FY 2017.
- (2) Ranking of diseases and conditions that predominately affect women are based on scientific relevance and disease prevalence, in descending order.
- (3) Only four ICs provided funding in this category.

Question:

What is the current NIH-wide investment in research in pregnant women?

Response:

Maternal health covers the health of women during the pre-pregnancy, pregnancy, and postpartum periods. To better track spending on this critically important public health issue, NIH created an official reporting category in 2017 for maternal health, which includes both maternal morbidity and death. The total spending for maternal health in 2018 was \$303 million.³ This new resource clearly shows that NIH currently funds research to address knowledge gaps in risk prediction, severe morbidity, optimal timing for delivery, maternal long-term outcomes, and data collection. For research directly related to pregnancy, NIH spent \$419 million in 2018.²

NICHHD leads the NIH's research portfolio on pregnancy. NICHHD's new strategic plan⁴ was published in September and will guide research activities for the next five years. Two of the five broad themes will address pregnancy research: *Setting the Foundation for Healthy Pregnancies and Lifelong Wellness* and *Advancing Safe and Effective Therapeutics and Devices for Pregnant and Lactating Women, Children, and People with Disabilities*. In addition to these themes, cross-cutting topics such as health disparities and disease prevention are integrated into all five research themes.

NICHHD has several existing research initiatives and activities that seek to improve health outcomes for pregnant women. PregSource®⁵ is a crowdsourcing research project that will help researchers learn how women from a variety of backgrounds experience pregnancy, which may lead to improvements in care. The Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) submitted a report⁶ to the Secretary of Health and Human Services in 2018 with recommendations about how to improve gaps in knowledge and research

³ https://report.nih.gov/categorical_spending.aspx

⁴ https://www.nichd.nih.gov/sites/default/files/2019-09/NICHHD_Strategic_Plan.pdf

⁵ <https://www.nichd.nih.gov/research/supported/pregsource>

⁶ https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf

on safe and effective therapies for pregnant women and lactating women. Phase II of the Task Force is expected to issue a plan on how to implement those recommendations in 2020. The Task Force has several NIH ICOs that are members. NICHD also actively coordinates its research efforts with other ICOs to better understand conditions that occur in pregnancy, such as preeclampsia (NHLBI), gestational diabetes (NIDDK), and postpartum depression (NIMH). For example, NHLBI is funding a study to leverage existing cohorts to search for biomarkers that could help predict preeclampsia, as well as subsequent CVD.⁷ To improve treatment of the most common complication, chronic hypertension, NHLBI is funding the Chronic Hypertension and Pregnancy (CHAP) trial, a randomized, multicenter trial of 2,400 pregnant women to evaluate the benefits, effectiveness, and potential harms of using medication to treat mild chronic hypertension in pregnancy.⁸

Question:

How NIH is prioritizing this type of work, and how is this research coordinated across the NIH?

Response:

NIH's Office of Research on Women's Health (ORWH) coordinates women's health research through the NIH Coordinating Committee on Research on Women's Health (CCRWH). The CCRWH includes representation from the NIH Institute, Center, and Office (ICO) Directors or their senior-level designees. In 2019, NIH implemented a *2019-2023 Trans-NIH Strategic Plan for Research on Women's Health*⁹ as a framework for scientific planning within the ICs, and for coordinating women's health research priorities across the NIH. This strategic plan emphasizes the importance of taking a life course approach in research to improve the health of girls and women.

⁷ https://projectreporter.nih.gov/project_info_description.cfm?aid=9595070&icde=0

⁸ www.nhlbi.nih.gov/news/2019/chronic-hypertension-pregnancy-treat-or-not-treat

⁹ https://orwh.od.nih.gov/sites/orwh/files/docs/ORWH_Strategic_Plan_2019_02_21_19_V2_508C.pdf

Questions for the Record for Dr. Perez-Stable

Submitted by Congresswoman Roybal-Allard

Disparities in Maternal Health

Given the growing disparities in maternal health – specifically related to maternal mortality – in this country, the NIH houses several research networks that have been highly efficient and successful in conducting clinical research that has changed the practice of medicine, like the Maternal Fetal Medicine Units Network (MFMU) at the NICHD.

Question: How is NIMHD working with NICHD to leverage these types of networks and tackle the public health crisis of maternal mortality, especially among Black and Native American women?

Response: NIMHD staff serve as a representative of the NIH Maternal Health Working Group, which is co-chaired by NICHD and the Office of Research on Women's Health (ORWH). This workgroup is focused on developing innovative and collaborative ideas to advance maternal health, especially in relation to maternal mortality and severe morbidity. The question of ethnic and racial disparities in this area will be examined by the working group as these relate to African American and American Indian women.

In addition, NIMHD is a member of the NIH Pediatric Research Consortium (N-PeRC), a trans-NIH initiative that began in June 2018 to capitalize on pediatric research expertise and resources across NIH's 27 Institutes and Centers through increased collaboration. The consortium meets several times a year to discuss scientific opportunities and potential new areas of collaboration, including efforts to address maternal mortality.

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) is the lead for the consortium. NIH support for pediatric research currently totals more than \$4 billion. N-PeRC aims to harmonize these activities across institutes, explore gaps in the overall pediatric research portfolio, and share best practices to advance science.

Other examples of collaboration on maternal mortality and morbidity at NIH include the National Heart, Lung, and Blood Institute (NHLBI) leveraging NICHD's Maternal Fetal Medicine Units Network, to fund a multicenter, randomized clinical trial of 1,500 women to evaluate pravastatin for women at risk of recurrent preeclampsia, a common complication of pregnancy that can put both mother and child at risk of death. In addition, NHLBI is also partnering with NICHD in a multi-site phase III "SLEEP" trial to assess whether treatment of obstructive sleep apnea with continuous positive airway pressure (CPAP) in pregnancy will result in a reduction in the rate of hypertensive disorders of pregnancy.

Elimination of HIV/AIDS Transmission

President Trump announced during the State of the Union that the Surgeon General will be working to eliminate the transmission of HIV/AIDS by 2030.

Question: How has NIMHD been coordinating efforts and engaging with health care practitioners and others to achieve this goal?

Response: The National Institute on Minority Health and Health Disparities (NIMHD) has several active grants funded through initiatives aimed at preventing and treating HIV in high-risk, underserved populations. These initiatives include two youth-focused programs. One, *Behavioral Interventions to Prevent HIV in Diverse Adolescent Men Who Have Sex with Men*, focuses on adolescents aged 18 and under. The other, *Engaging Youth and Young Adults from Health Disparity Populations in the HIV Treatment Cascade*, focuses on youth aged 12-25 who have HIV. NIMHD is also addressing the pronounced racial/ethnic disparities in HIV prevention and treatment through an initiative on *Research on Pre-Exposure Prophylaxis (PrEP) to Prevent*

HIV in Health Disparity Populations, and Prevention and Treatment Research to Address HIV/AIDS Disparities in Women in the US. Planned future initiatives address implementing evidence-based interventions and practices with underserved health disparity populations, including *Multi-Level HIV Prevention Interventions for Individuals at the Highest Risk of HIV Infection or Transmission*, and *Promoting Viral Suppression of Individuals from Health Disparity Populations Engaged in HIV Care*.

NIMHD Proposed Reorganization

We have heard that NIMHD would like to conduct an internal reorganization but needs congressional approval in order to do this.

Questions:

1. Can you provide us with the details on this proposed reorganization?
2. How would this proposed reorganization improve or increase the capacity of the NIMHD to address persistent health disparities in our minority communities?

Response: The National Institute of Minority Health and Health Disparities (NIMHD) is considering a reorganization to optimize resources to advance the science of minority health and health disparities, particularly regarding the kinds of grants and areas of research that NIMHD funds. New challenges are expected to emerge as the number of individuals from disparity populations in the U.S. increases and the science of minority health and health disparities continues to evolve.

Questions for the Record for Dr. Langevin

Submitted by Congresswoman Roybal-Allard***Alternative Pain Management***

According to a 2017 *National Bureau of Economic Research* study, American's perceive pain at significantly higher rates than most other countries, and we are consuming more prescription pain killers than almost all other countries combined. Our addiction to being pain free has exacerbated an opioid crisis that took 47,000 lives in 2017. Certainly we can all agree that there is a great need for alternative pain relief methods.

Question 1: NCCIH is one of the many institutes involved in NIH's HEAL Initiative. How are you prioritizing this mission of battling addiction, and what are some of the most promising non-pharmacologic treatments for pain relief that your Center has studied?

Response: In the battle against the opioid misuse epidemic, the National Center for Complementary and Integrative Health (NCCIH) prioritizes research related to pain and pain management strategies and dedicates approximately 40 percent of its budget to this type of research. The rationale is two-fold. First, the United States is experiencing a pain epidemic that helps fuel the opioid epidemic. A recent study conducted by NCCIH scientists analyzing 18 years of Medical Expenditure Panel Survey (MEPS) data found that the percentage of U.S. adults suffering from a painful condition has increased significantly from 120.2 million (32.9 percent) in 1997/1998 to 178 million (41 percent) in 2013/2014. This increase in pain correlated with an increase in the use of strong opioids, like fentanyl, morphine, and oxycodone, for pain management among adults with severe pain that interferes with daily activities -- from 4.1 million (11.5 percent) in 2001/2002 to 10.5 million (24.3 percent) in 2013/2014. Unfortunately, research has shown that with long-term use, opioids lose their effectiveness resulting in higher doses needed for pain management, which can lead to increased risk for overdose and death and can increase pain sensitivity.

Second, patients with opioid use disorder (OUD) often continue to experience chronic pain and need long-term, nondrug strategies to manage their pain that will not increase their likelihood of relapse.

NCCIH supports research on behavioral strategies to improve adherence to the medical treatment of opioid use disorder, reduce opioid cravings, and manage symptoms of chronic pain that many individuals with OUD experience. Nondrug techniques provide additional tools that can be used alone or in combination with pharmacologic treatments to help manage pain. These approaches influence the biological, psychological, and social factors that contribute to the pain response.

In June 2018, the Agency for Healthcare Research and Quality (AHRQ) published a systematic review evaluating the state of the science of noninvasive nonpharmacological treatment for chronic pain. This review relied heavily on NCCIH-sponsored research and concluded that there is good evidence that exercise, cognitive behavioral therapy, spinal manipulation, massage, mindfulness-based stress reduction, yoga, acupuncture, tai chi, and qigong can reduce pain for specific chronic pain conditions.

As part of the HEAL initiative, mindfulness-based stress reduction is being evaluated in a large pragmatic “real-world” clinical trial within the civilian healthcare system. Mindfulness is a form of meditation that, among other strategies, trains individuals to focus on the present moment without reacting to it. This intervention has been shown to activate the same pain-relieving regions of the brain as opioids, as well as regions involved in processing attention and emotional responses to sensations. These results suggest that mindfulness can impact psychological interpretation of pain signals, and the pain-relieving pathway utilized by opioids. Should these interventions be proven to be effective, this research will facilitate the adoption and uptake of these approaches in real world health care settings.

Also, as part of the HEAL initiative, acupuncture is being evaluated for the treatment of chronic low back pain in patients 65 years of age or older in a pragmatic clinical trial. Acupuncture is also showing promise for pain management and is a key component of traditional Chinese medicine that has been practiced for thousands of years to treat pain and other conditions.

Between 1999 and 2018, NCCIH supported 175 scientific research projects related to acupuncture, which have contributed to more than 1,400 peer-reviewed scientific publications. Results from these and other studies suggest that acupuncture can help ease types of chronic pain such as low-back pain, neck pain, migraine and osteoarthritis/knee pain.

The potential benefits of acupuncture for pain management have been embraced within the military and veteran populations, which experience a higher prevalence of chronic pain than the general population. Through an interagency partnership, NIH, DoD, and VA are supporting a multi-component research project focusing on nondrug approaches for pain management addressing the needs of service members and veterans. This initiative will provide important information about the feasibility, acceptability, safety, and effectiveness of nondrug approaches in treating pain. Types of approaches being studied include mindfulness/meditative interventions, movement interventions (e.g., structured exercise, tai chi, yoga), manual therapies (e.g., spinal manipulation, massage, acupuncture), psychological and behavioral interventions (e.g., cognitive behavioral therapy), integrative approaches that involve more than one intervention, and integrated models of multi-modal care. Because the research is leveraging the DoD and VA health care systems, these approaches if proven effective, can be more easily implemented within these health systems.

Question 2: How are you disseminating your findings to hospitals, clinicians and health care consumers so that we can begin to change attitudes and behaviors around prescription pain medications?

Response: NCCIH disseminates research through a website (NCCIH.NIH.Gov), the NCCIH Information Clearinghouse, and at scientific meetings/conferences. The Center provides resources targeted to different types of audiences. For the general consumer, NCCIH has a “Health Topics A-Z” series that provides research-based information about complementary health approaches and specific health conditions. NCCIH recently launched a new initiative called “Know the Science” that seeks to explain scientific topics related to health research. The materials are designed to provide content and engagement for consumers to familiarize them with the science not only on topics in complementary and integrative health, but those common

to all areas of health research. For the scientific and medical communities, the Center publishes a monthly e-newsletter called the "*NCCIH Clinical Digest*" that summarizes the state of the science on complementary and integrative health practices for a specific health condition (pain, diabetes, cancer, sleep disorders, etc.). It includes links to relevant clinical guidelines, scientific research, continuing medical education resources, and provides resources for interested patients.

Committee on Appropriations
Labor, Health & Human Services, and Education Subcommittee
*Investments in Medical Research at Five Institutes and Centers of
the National Institutes of Health (9.25.19)*

Questions for the Record

Submitted by Congresswoman Watson Coleman

Maternal Health and Health Access

During our September 25th hearing, Dr. Perez-Stable mentioned that health access was one of a couple factors driving higher maternal mortality and morbidity rates in the black community.

Question: Would the NIH consider looking at insurance rates of pregnant mothers and how that may affect their health outcomes, as well as that of their babies?

Response: Multiple factors contribute to pregnancy-related severe morbidity and mortality. These include, but are not limited to, the following: preventive care; chronic diseases; quality of care before, during, and post-pregnancy; individual social determinants of health; and structural factors. The NIH is currently supporting various projects addressing the role of insurance and health outcomes. Currently, Medicaid coverage is required for low income pregnant women up to 138 percent of the Federal Poverty Level (FPL); most states offer coverage to pregnant women above 138 percent FPL. Both the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Heart, Blood, and Lung Institute are supporting projects investigating the role of Medicaid coverage on maternal and infant health. Also, the National Institute on Minority Health and Health Disparities is supporting several projects focused on the impact of healthcare access, utilization, and quality of care among health disparity populations over the last ten years. Research related to maternal mortality will continue to be a priority of NIH to discover ways to address these unnecessary adverse health outcomes.

Autism and Health Disparities

We know 1 in 59 children are on the autism spectrum. And there are significant disparities when it comes to the ability to obtain a diagnosis and access services. For example, the most recent CDC estimates have shown that the autism prevalence rate is higher for white children than African American children, and even higher when compared to Latinx children. This suggests there are missing diagnoses, or identification disparities in communities of color. Furthermore, recent research has shown that children with autism spectrum disorder have 4 times higher odds of having unmet health care needs than children without disabilities and 2 times higher even compared with other children with disabilities.

Question: Does the NIH fund any research into these autism-related disparities? If not, does it have plans to?

Response: Autism spectrum disorder (ASD) is characterized by persistent deficits in social communication and social interaction across multiple contexts, and restricted, repetitive patterns of behavior, interests, or activities. Symptoms, which generally appear in the first two years of life, can cause clinically significant impairment in social, occupational, or other areas of functioning. In order to improve the lives of those impacted, NIH funds a variety of research to increase our understanding of ASD, including research on the causes, diagnosis, early intervention, and treatment of ASD.

Data from the Centers for Disease Control and Prevention (CDC) indicate that ASD prevalence estimates vary by sex and race/ethnicity. For example, males were four times more likely than females to be identified with ASD; and the prevalence among non-Hispanic white children (17.2 in 1000) is higher than that for non-Hispanic black children (16.0 in 1000) and Hispanic children (14.0 in 1000).¹ Data from a previously reported comparison of ASD prevalence estimates from 2002, 2006, and 2008 suggested greater increases in ASD prevalence among black and Hispanic children compared with those among white children.² The authors note that reductions in disparities in ASD prevalence for black and Hispanic children might be attributable, in part, to

¹ https://www.cdc.gov/mmwr/volumes/67/ss/ss6706a1.htm?s_cid=ss6706a1_w

² <https://www.ncbi.nlm.nih.gov/pubmed/22456193>

more effective outreach directed to minority communities. Research continues to explore how much of the rise in ASD prevalence is due to better ascertainment, changing diagnostic criteria, or narrowing of disparities in ASD identification in minority populations, and how much of the rise in ASD prevalence may be due to increased incidence.

Race, culture, socioeconomic status (SES), and community may play a significant role in ASD diagnosis. While ASD is usually diagnosed by age four, on average, African American children are diagnosed 1.5 years later than their white counterparts and are more likely to have received another diagnosis before an ASD diagnosis.³ NIH is currently funding research to develop strategies for early screening to identify ASD at the earliest age possible to learn how autism develops and to pave the way for newer, earlier, and better interventions focused on improving quality of life. Recognizing that there may be different barriers to screening and treatment in different communities, NIH is investing in studies aimed at understanding and reducing these barriers. NIH research aimed at improving the understanding of the early behavioral signs of ASD and updating diagnostic tools has enabled trained clinicians to diagnose ASD much earlier, and screening for ASD in the second year of life is now recommended by the American Academy of Pediatrics.⁴ In addition, NIH-funded researchers are studying the use of telemedicine tools to reduce disparities related to the early identification of ASD among diverse and underserved communities.^{5,6}

Regarding access to care, NIH-funded researchers are studying factors that impact access to treatment for ASD for underserved populations. These researchers have shown that children who receive treatment earlier have better long-term functional outcomes.⁷ As with diagnosis, socioeconomic and sociocultural factors may also impact access to and enrollment in early intervention services, with low SES minority children being at increased risk for delayed enrollment into early intervention services than children from high SES classes.⁸ NIH recognizes that screening, identification, and initiation of intervention are separate, but linked, processes,

³ <https://www.ncbi.nlm.nih.gov/pubmed/19106426>

⁴ <https://www.nimh.nih.gov/about/director/messages/2019/progress-and-priorities-in-autism-research-its-beginning-to-feel-a-lot-like-springtime.shtml>

⁵ <https://clinicaltrials.gov/ct2/show/NCT03847337>

⁶ https://projectreporter.nih.gov/project_info_description.cfm?aid=9859231

⁷ <https://www.ncbi.nlm.nih.gov/pubmed/18349708>

⁸ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5693721/>

and there is often a delay in initiating services after a diagnosis. Several NIH-funded research projects are underway to evaluate interventions that aim to promote early detection and entry into intervention, implemented in diverse, real-world community settings. Examples include research using a patient navigator model in which individuals trained in community and health system resources for ASD help vulnerable populations overcome psychological and logistical hurdles to care using a theory-based care management strategy designed to reduce disparities in access to care;⁹ and multi-stage screening programs involving pediatricians, parents, and early intervention providers to encourage screening and early access to interventions by low SES communities.¹⁰ NIH also recognizes the need to improve access to health care, and improve sensitivity among the healthcare workforce to the special needs of individuals with ASD. NIH is funding research to understand the unmet mental healthcare needs of the ASD community, including an understanding of how these factors differ by race and ethnicity or between rural and urban residence.¹¹

There is also a disparity in the availability of biological resources from diverse populations for basic science research into risk and causes of ASD. Researchers utilize large genomic databases to investigate how rare genetic variations, mutations, and abnormalities affect an individual's risk for autism. Recognizing that individuals with self-reported African ancestry (African-Americans) are under-represented in these databases, NIH has funded a large Autism Center of Excellence to recruit participants with African ancestry and analyze the data.¹²

NIH recognizes the importance of obtaining input from the ASD community in order to understand the challenges related to disparities in autism and formulate research questions. NIH, other federal departments and agencies, and private organizations recently discussed racial and ethnic disparities in autism at the July 24, 2019 meeting of the Interagency Autism Coordinating Committee (IACC).¹³ The IACC is a federal advisory committee that coordinates federal efforts and provides advice to the Secretary of Health and Human Services on issues related to ASD.

⁹ https://projectreporter.nih.gov/project_info_description.cfm?aid=9768553

¹⁰ https://projectreporter.nih.gov/project_info_description.cfm?aid=9505979

¹¹ https://projectreporter.nih.gov/project_info_description.cfm?aid=9994570

¹² https://projectreporter.nih.gov/project_info_description.cfm?aid=9910166

¹³ <https://iacc.hhs.gov/meetings/iacc-meetings/2019/full-committee-meeting/july24/#agenda>

The July meeting included presentations from researchers working on projects related to autism and disparities, as well as parents and advocates representing ASD organizations that serve the African American and Latino/Hispanic communities on the needs and challenges experienced by underserved populations. In addition, the IACC's *2016-2017 Strategic Plan for ASD*, which provides guidance to government and partner organizations on priorities for autism research, services, and policy, addresses disparities in access to services for individuals with ASD.¹⁴ In the plan, the Committee included a new objective under Question 5: "*What kinds of services and supports are needed to maximize quality of life for people on the autism spectrum?*" The objective addresses reducing disparities in access and outcomes for underserved populations, highlighting the need to support research to understand and develop strategies concerning health inequity and disparities in services access and utilization for racial/ethnic minorities. The IACC was recently reauthorized under the Autism CARES Act of 2019 and will continue discussions about how to address disparities.

Sarcoidosis

This is a follow up from the last NIH hearing

Question: Dr. Perez-Stable, would you be able to provide an update on NIH research into Sarcoidosis?

Answer: Sarcoidosis is a rare condition in which groups of immune cells form lumps, called granulomas, in various organs of the body causing fatigue or fever. While sarcoidosis can affect any organ, it affects the lungs in 90 percent of cases. The incidence of sarcoidosis is estimated to be between 11-40 cases per 100,000 in the United States.¹⁵ Sarcoidosis affects people of all races, with the highest rates among African Americans at about 34 cases per 100,000 people.¹⁶ Many people recover with few or no long-term problems, but some may experience chronic symptoms or build-up of scar tissue (called pulmonary fibrosis when it occurs in the lungs). In rare cases, sarcoidosis can be fatal.¹⁷

¹⁴ https://iacc.hhs.gov/publications/strategic-plan/2017/strategic_plan_2017.pdf

¹⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6196636/>

¹⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4314818/>

¹⁷ <https://www.sciencedirect.com/science/article/pii/B9780080552323607883?via%3Dihub>

The National Heart, Lung, and Blood Institute (NHLBI) is committed to understanding the causes of sarcoidosis, developing better diagnostics and treatments, and improving outcomes for patients. NHLBI-funded studies have revealed that both genetics and environment, including agricultural work and insecticide exposure, play a role in sarcoidosis.^{18,19}

In 2015, NHLBI sponsored a workshop entitled “Leveraging Scientific Advancements to Understand Sarcoidosis Variability and Improve Outcomes” to assess the current state of knowledge of the genetic, environmental, and immunologic basis of sarcoidosis.²⁰ Participants noted that disparities in outcomes exist by race, ethnicity, sex, and socioeconomic groups, with the highest mortality rates among African Americans.²¹ A key focus was the promise of applying genomic and other ‘omics’ analyses and systems biology to advance understanding of disease mechanisms, facilitate biomarker discovery, and accelerate the development of novel therapies. In response, the NHLBI includes patients with sarcoidosis in its multi-ethnic TransOmics for Precision Medicine (TOPMed) program that integrates whole-genome sequencing data with molecular, behavioral, imaging, environmental, and clinical data.²²

Other studies are investigating possible biomarkers that could improve diagnosis of sarcoidosis, as well as guide new targeted interventions and their evaluation in clinical trials. In an observational study, NHLBI-funded researchers discovered that distinct patterns in the lung microbiome are characteristic of distinct sarcoidosis subtypes.²³ An ongoing study is examining microbial and immune interactions that might contribute to sarcoidosis progression and resilience.²⁴

An analysis of data from two existing NHLBI-funded cohorts identified higher levels of mitochondrial DNA in airway fluids and blood as a biomarker for extrapulmonary organ involvement and worse prognosis, especially in African American patients.²⁵ Another study

¹⁸ https://projectreporter.nih.gov/project_info_description.cfm?aid=9418080

¹⁹ <https://www.ncbi.nlm.nih.gov/pubmed/15347561>

²⁰ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5822412/>

²¹ <https://www.ncbi.nlm.nih.gov/pubmed/29087725>

²² <https://www.nhlbiwgs.org/>

²³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4627423/>

²⁴ https://projectreporter.nih.gov/project_info_description.cfm?aid=9632837

²⁵ <https://erj.ersjournals.com/content/54/2/1801762.long>

found that measuring immune signaling molecules called cytokines in blood could help identify patients at risk for progression.²⁶

To improve diagnosis and earlier intervention, NHLBI supports research on the use of radiomics—a method of using qualitative and quantitative data analysis of clinical images to uncover disease characteristics—to identify new, more refined subtypes of sarcoidosis.²⁷ In a recently published study, researchers showed that radiomic measures correlate with lung function and stage of disease in patients with sarcoidosis.²⁸

Another key priority is to improve treatments for sarcoidosis. Current treatments involve efforts to reduce inflammation, often through the use of corticosteroids. While useful in acute cases, long-term benefits of corticosteroids are unclear as they have not been found to reduce disease progression.²⁹ Since previous studies have shown that smokers are less likely to develop sarcoidosis, possibly as a result of the immune suppression effects of nicotine, researchers are looking to the anti-inflammatory properties of nicotine as a potential treatment for the disease.³⁰

Ongoing research into the mechanisms of sarcoidosis is helping to reveal potential new targets for therapy. For example, investigators recently discovered that a certain protein is elevated in a mouse model of fibrosis and that blocking this protein reduced fibrosis in the mice.³¹

Researchers are also evaluating an oral medication to inhibit the enzyme chitotriosidase, which has been implicated as a driver of sarcoidosis.³²

Another innovative treatment alternative is the use of antimicrobials to target mycobacteria in pulmonary sarcoidosis. NHLBI-funded clinical trials are investigating antimycobacterial therapy to improve lung function.³³

²⁶ <https://www.ncbi.nlm.nih.gov/pubmed/?term=31128616>

²⁷ https://projectreporter.nih.gov/project_info_description.cfm?aid=9738371

²⁸ <https://www.ncbi.nlm.nih.gov/pubmed/?term=31196947>

²⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6171107/>

³⁰ https://projectreporter.nih.gov/project_info_description.cfm?aid=9069953

³¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6263177/>

³² https://projectreporter.nih.gov/project_info_description.cfm?aid=9775612&icde=46676408

³³ <https://clinicaltrials.gov/ct2/show/NCT02024555>

Topic: Diversity of PI's

The NIH is on track to fund the most investigators in its history.

Question: Can you share a breakdown of this class by race; whether they attended a public or private undergraduate institution, and if it was a minority serving institution (MSI); and whether their post-graduate institution was a public or private, or an MSI?

Response: NIH is currently reviewing the accuracy and completeness of its FY 2019 grant award data as part of its annual quality control review process. NIH anticipates having appropriate data and analyses completed early in calendar year 2020 to address this request.

Investigator race information is considered sensitive, personally identifiable information. Thus only aggregated, de-identified data on race would be provided to protect privacy. Race is a self-reported field and researchers have the option to not indicate a specific race/ethnicity on their NIH profile.

Please also note that analyses would focus on institutions from which investigators received their terminal degree only. This is because NIH does not collect data for all principal investigator classifications on undergraduate degrees and there is a greater level of standardization of terminal degrees. Moreover, a researcher may have received a bachelors degree from multiple different institutions, complicating the analysis.

WEDNESDAY, OCTOBER 16, 2019.

E-CIGARETTES: AN EMERGING THREAT TO PUBLIC HEALTH

WITNESSES

ANNE SCHUCHAT, M.D., PRINCIPAL DEPUTY DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION

RENEE D. COLEMAN-MITCHELL, MPH, COMMISSIONER, CONNECTICUT DEPARTMENT OF PUBLIC HEALTH

SALLY SATEL, M.D., RESIDENT SCHOLAR, AMERICAN ENTERPRISE INSTITUTE

BONNIE HALPERN-FELSHER, PH.D., PROFESSOR OF PEDIATRICS, EXECUTIVE DIRECTOR OF THE STANFORD TOBACCO PREVENTION TOOLKIT

MEREDITH BERKMAN, CO-FOUNDER AND PARENT, PARENTS AGAINST VAPING E-CIGARETTES (PAVe)

Ms. DELAURO. The subcommittee will come to order.

Before I begin, I would like to welcome our guests. In the first panel this morning, we have Dr. Anne Schuchat, Principal Deputy Director for the Centers for Disease Control and Prevention. She is the staff lead for the investigation aspect.

Then in our second panel, we will have the following witnesses. Renee Coleman-Mitchell, commissioner of the Connecticut Department of Public Health. It was wonderful to speak with the commissioner at an event that we did several weeks ago about vaping. We were hosted at Yale New Haven Hospital, and I just want to say thank you, thank you, thank you for your dedication to this issue.

We also have Dr. Sally Satel, resident scholar, the American Enterprise Institute; Dr. Bonnie Halpern-Felsher, professor of pediatrics and the executive director of Tobacco Prevention Toolkit at Stanford University; and Meredith Berkman, co-founder of Parents Against Vaping E-cigarettes, PAVe, P-A-V-e.

I will introduce them again before their testimony, but we are so delighted that you could all join with us this morning.

I know that our full committee chair is going to be here shortly, and I mentioned Congresswoman Lowey because this issue on e-cigarettes and vaping has been a signature issue for her. She has focused on it over and over again over the years.

This is an important hearing. We are here for several reasons, to hear from the CDC on their investigations into e-cigarettes related to lung illness and death. We are here to talk about the ongoing Federal response to the public health crisis of e-cigarettes. We know that the increased numbers of young people vaping have really created a public crisis.

We are here to identify the public policy remedies we need to be advancing to address this public health crisis, and we are here to highlight the important investments we need to be making through

the Labor, HHS appropriations. These investments include tobacco prevention and awareness activities and our national public health data infrastructure.

There are multiple areas of focus because this is a multipronged crisis. One track is the rising incidence of lung injuries and deaths from vaping and e-cigarettes. The other is the youth epidemic, which is hooking the next generation on nicotine products.

These are the symptoms, but at the heart of this issue is a fundamental question about the use of e-cigarettes and vaping. Are the products safe? Are they unsafe? Do we know? Do we have the scientific data? And how do we regulate these products?

Of course, the CDC falls under this committee's jurisdiction. The FDA does not, although I do also sit on the Agricultural Appropriations Committee, which has jurisdiction over the Food and Drug Administration.

But the work of these two agencies is critical and linked. Yet while the CDC has routinely warned of the health risks of youth vaping, starting back in 2013—and I would mention to CDC, it was 2013 they published a report highlighting the doubling in youth cigarette use during 2011–2012.

Again, in 2016, they collaborated with the Surgeon General to release the Surgeon General's report, entitled "E-cigarette Use Among Youth and Young Adults." Then again, in 2018, they again worked with the Office of the Surgeon General, writing and launching of an e-cigarette advisory to bring awareness to relevant audiences—teachers, parents, clinicians, et cetera. So the CDC has played a very constructive role in making information known about e-cigarettes.

The result—

[Pause.]

Ms. DELAURO. I am going to interrupt myself for a second just to say that the chair of the Appropriations Committee, and I mentioned this a few minutes ago, Congressman Lowey, that this has been a signature issue of yours, you know, for a very, very long time, and one that is near and dear to your heart.

The CHAIRWOMAN. Thank you.

Ms. DELAURO. I also might add you will always and ever be the chair of the Appropriations Committee. So there, my friend, anyway.

The CHAIRWOMAN. Actually, I am not standing because I want to speak out of turn. I am just trying to adjust this chair. [Laughter.]

Ms. DELAURO. We have got to get rid of the chairs. The chairs are too big. The chairs are too big.

The CHAIRWOMAN. Thank you for your kind words, as long as I am standing.

Ms. DELAURO. Right. I was saying the CDC has, I think, routinely warned of the health risks. I will just also say that the FDA has appeared to have ignored these warnings. It has taken no meaningful action to regulate e-cigarette products, though the Congress gave it the authority to do so in 2009 by talking about pre-market review of these products.

The result of which is that we now have a public health crisis. The Centers for Disease Control and Prevention has confirmed vaping-related lung illnesses have risen to over 1,000 cases and

now 26 deaths, with the numbers climbing each week. The FDA is investigating the link between e-cigarettes and seizures, and the U.S. Surgeon General has warned that e-cigarettes pose risks for brain development, the human respiratory system, and lifelong nicotine addiction.

In Connecticut, we had our first fatality, and one fatality is over the line. People should not be dying. The other part of this crisis is the youth vaping epidemic. It was on a cover of Time magazine, and the headline read—and I quote—“The New American Addiction: How Juul Hooked Kids and Ignited a Public Health Crisis.”

According to preliminary results from CDC’s 2019 National Youth Tobacco Survey, 1 out of 4 high school students have used e-cigarettes within the last 30 days. This youth vaping epidemic has nearly tripled since 2017. In my home State, vaping is now the most common form of youth smoking among Connecticut high school students. The commissioner of the Connecticut Department of Public Health will reference this, but there is clear data demonstrating that as use of combustible cigarettes among teens is dropping, e-cigarettes are rising.

Now I spoke to my 14-year-old granddaughter. I think we are all speaking to our grandchildren at ages 13 and age 14. She is the first year in high school in Washington, D.C. And I said, “Rigs, tell me, are people vaping?”

And she said, “Bubby, it is everywhere. Everyone is vaping.” She even sent me some articles in their school newspaper of—I have got to get her hooked on wanting to be—you know, get involved in politics and so forth and so on. [Laughter.]

Ms. DELAURO. But she sent me the articles showing me what her school is doing to notify parents of the dangers of Juul, of vaping, and of e-cigarettes.

I recently spoke at an event with Dr. Pnina Weiss, medical director for Pediatric Pulmonary Function Laboratory at Yale New Haven Children’s Hospital. She ran through the chemicals that are present in these devices.

Ethylene glycol, which is used in antifreeze; propylene glycol, which is used as toner for laser printers; vitamin E oil, which is under investigation and implicated in the outbreak of lung illnesses; fine particles and carcinogens; fruit flavorings to attract youth; and nicotine, which is the addictive chemical in cigarettes that hurts children’s brain development. One Juul pod has as much nicotine as one pack of cigarettes.

You know, we have such little information about the chemical additives. One of them that was brought to my attention was a chemical called diacetyl. I dealt with diacetyl many, many years ago because it was in manufacturing. It causes something called “popcorn lung,” which is a very serious lung disease that we found.

So this is a cocktail. All of these pieces is a cocktail, and it is a recipe for disaster.

Further compounding the risk to youth is the fact that there is no approved nicotine replacement therapy for children under the age of 18, that we do not know what will happen to kids who turn teen vaping into a lifelong addiction.

There is a lack of scientific data. A lack of FDA approvals is an important factor in this discussion that I want to touch on briefly.

Despite the anecdotal claims that some businesses have made, there is no data demonstrating the long-term safety of vaping. There is no evidence that e-cigarettes are successful as a cessation tool, which experts have confirmed. And there is no e-cigarette that has been FDA approved as a smoking cessation device.

Let me just—this was in 2018, the National Academies of Sciences, Engineering, and Medicine report, they concluded—and I quote. “Overall, there is limited evidence that e-cigarettes may be effective aids to promote smoking cessation.”

So we don’t have the scientific data to move forward. Anecdotes, company claims must not be stymying the bipartisan push to protect our communities, especially when the science is so clearly on our side.

Today, the Energy and Commerce Committee is holding a hearing on a comprehensive legislative package that, among other things, would ban kid-friendly flavors. The Judiciary Committee is marking up my bill, the Preventing Online Sales of E-cigarettes to Children Act. This bipartisan bill, which I first introduced in 2015, will close an existing loophole in Federal law by mandating age verification of online sales and deliveries of e-cigarette and vapor products.

Despite announcing a proposal, which the administration did—to their credit—to ban flavored e-cigarettes that was well over a month ago, we have not seen anything yet. And we are now seeing industry pressure the administration into exempting mint and menthol flavored e-cigarettes from its flavor ban, when these are among the most popular flavors among youth.

Such action is necessary because, clearly, industry self-regulation is not working. Past time for the FDA to uphold its mission as a regulatory agency, use their authority to protect people from these harmful products.

Again, I mention that this goes back to 2009. The Congress, the Congress said, we gave the FDA the authority to regulate all tobacco products, including e-cigarettes. The bipartisan Family Smoking Prevention and Tobacco Control Act, or TCA, gave FDA the authority to regulate new tobacco products before they enter the market, and that includes e-cigarettes. FDA has not. Instead, it has allowed dangerous products to come onto the market. It has exempted e-cigarettes from premarket review.

And again, what that review would have said is, is this product safe? It would have collected scientific data to test whether or not it was safe. The FDA uses something called “enforcement discretion” and allowed the devices to be sold.

I might add, I just want to say that in the past two administrations—this delay just has not been caused now. This delay occurred under the prior administration as well, and the delay continues. This is now 10 years of this product, and we now know that the industry is continuing to push to see if there an opportunity for a future delay on what we talked about in terms of applications in May 2020. So there is this delay process, which we have to break through.

Here in our committee, the Labor, HHS Subcommittee, we have been advancing funds that could be a crucial part of the response. In the House-passed fiscal year 2020 Labor, HHS appropriations

bill, we include a \$40,000,000 increase for CDC's tobacco prevention and cessation efforts. Its Office on Smoking and Health is committed to a world free from tobacco-related death and disease.

This crisis has demonstrated the need for the \$100,000,000 that we provide in fiscal year 2020 in the bill for a new initiative to begin addressing the gaps in our Nation's public health data infrastructure. I might add, and I say this to you and to my colleagues, the Senate bill—the Senate bill has not put an additional dime into these programs.

So I think this epidemic has spotlighted the gaps in our public health data infrastructure. I believe what we have done in this committee is the right thing in terms of increased funds, and we have to persuade our Senate colleagues to do the same.

When it emerged, the CDC had to create entirely new databases and systems. The process was neither speedy nor seamless. The first iteration crashed and burned in less than a week, system errors and bugs.

The second iteration required States to enter data by hand in a cumbersome, fragmented, and not automated file submission process. Yet further evidence that our public health data systems are too antiquated. They are in need of grave—a grave need of upgrades. Our systems still rely on obsolete technologies like faxes and compact disks.

To me, this is evidence as to why we need \$100,000,000 in the House-passed bill. But as I said, this is a crisis demanding more immediate action than our funding for fiscal year 2020.

I know many of our witnesses today have recommendations for what the Congress can do and should do. Please share with us your suggestions. We need your help, and we must act, and we need to act now.

Let me just turn this now over to my good friend from Oklahoma, the ranking member of the subcommittee, Congressman Tom Cole, for any remarks he may want to make.

Mr. COLE. Thank you, Madam Chair.

Before I begin my official remarks, it would be remiss of me, because I have not seen our chairman since her announcement that she is going to retire at the end of this Congress, to tell her how much we are going to miss her, how much we admire her and the manner in which she has led this committee as chairman and the manner in which she served it when she was ranking member, and all the years of service in all the capacities. You have been a Member's Member and an appropriator's appropriator. And just you are going to be sadly missed.

Now I was also going to throw my support to my chairman to be the distinguished ranking member of the full committee the next Congress. And so I am happy to head the Republican effort to get that done.

But again, both of you have served with such great distinction, and it has always been a pleasure. You were always at this committee when I was privileged to be the chairman. You are always here now. We know how interested you are in these subject matters, and I certainly associate myself with the ranking—excuse me, with the chairman's remark—or the chair's remark that we know

you are passionate and knowledgeable about this subject, and we appreciate your input and your guidance.

But more than that, we just appreciate you as a friend and as a leader in Congress for many, many years and wish you well in whatever you choose to do next.

The CHAIRWOMAN. I speak out of turn by just saying thank you. Thank you. And I really do think what I will miss most is all the friendships because we have had the opportunity to work across the aisle and, of course, all my friends on this side. So I want to thank you.

But I will be here about 15 more months. So we can do a lot of good work. Thank you for your kind words.

Mr. COLE. I know. I know. We look forward to working with you in those 15 months.

The CHAIRWOMAN. Thank you.

Mr. COLE. You bet. Thank you, Madam Chair.

Madam Chair, I want to again thank our chair for holding this important hearing. We have all been alarmed by the frequency of lung illnesses related to the use of electronic cigarette products. We are the third committee to hold a hearing in the last few weeks on this topic, and I am glad to see such a concerning issue getting serious, rigorous oversight and attention.

Over the last few months, the Centers for Disease Control and Prevention began an investigation into lung illnesses and deaths associated with e-cigarette use. Of particular concern is the relationship of those getting sick and the use of THC, the psychoactive compound found in marijuana.

Recent investigations in Wisconsin uncovered 10,000 THC vaping cartridges in a residential home. We know obtaining cartridges from friends or on the black market is dangerous. An overwhelming majority of the lung illnesses incidences are linked to THC-containing products, although certainly not all of them.

As we have seen States pass laws permitting greater access to marijuana, the market for devices using THC has exploded. This market growth has spawned a new black market for the production of THC-laced vape cartridges.

A report released from Wisconsin and Illinois found that nearly all THC-containing products reported were packaged, prefilled cartridges that were primarily acquired from informal sources, such as friends, family members, illicit dealers, or off the street. We should be cautious about associating THC-related misuse to appropriate use of nicotine-only products.

The same report found that over 80 percent of the nicotine-containing products were obtained from commercial sources. An over-reaction banning the sale or purchase of nicotine-based products could very well endanger more people. Studies have shown nicotine-based products do provide an alternative to traditional combustible cigarettes, an alternative that is safer and often assists smokers to abandon the use of cigarettes.

The reduction in the use of combustible tobacco is one of the largest public health achievements in the last decade. E-cigarettes have been part of this reduction, and they can continue to serve as a healthier alternative for adults who are current smokers. The CDC acknowledges that e-cigarettes have the potential to benefit adult

smokers when these products are used as a substitute for regular cigarettes.

The science around the benefits and associated risks of e-cigarettes is still new and in many cases not available. More research on the impact of these devices have for adult users is needed and currently underway at the National Institutes of Health.

If we remove nicotine-based e-cigarettes from store shelves, there is a strong likelihood adult smokers will continue using combustible tobacco, and that is something to be avoided.

While I believe the products should remain an option for adults, we can all agree that children should not be using these products under any circumstances. All necessary precautions should be taken to ensure e-cigarettes and associated products stay out of the hands of children. Moreover, companies selling these products should not be targeting children in marketing or advertising. These are principles on which we all agree.

And to its credit, the Trump administration has taken an aggressive approach to keep these products out of the hands of children. Under Food and Drug Administrator Gottlieb, the FDA issued more than 8,600 warning letters and imposed more than 1,000 civil monetary penalties or fines to retailers related to the sale of electronic nicotine devices to minors.

The FDA has also issued warning letters to companies related to marketing efforts that could target children. The Surgeon General has launched a prevention initiative aimed at educating young people on the dangers of e-cigarettes and information on how to stop the use of these products for those who may already be active users.

President Trump also announced last month that his administration would be looking at potential future regulatory action regarding the use of flavored products in e-cigarettes and the impact that such a decision could have on teenage usage.

I want to commend the work of the Centers for Disease Control and Prevention. The leadership by the CDC is critical to understanding the emerging public health issue.

Publicly, I want to thank Dr. Schuchat for her efforts and testifying here today. Doctor, you have come to the Hill several times in the last few weeks for several committees, and I am sure you will be inviting back more in the future. We appreciate your service.

In the span of a few weeks, the CDC has set up a response team to track, respond, and inform all interested parties on this troubling public health issue. CDC is sending assistance to States, supporting lab tests to learn more about the illnesses, and providing guidance to public health departments and clinicians nationwide. Their work here demonstrates why investments in our public health infrastructure can prove critical.

A complicated issue that involves coordination amongst enforcement, research, testing, clinical diagnostics, and an ongoing public awareness campaign demands a public health infrastructure that can mobilize and respond rapidly, and that is exactly what CDC has done in this case.

I also want to thank our second panel of witnesses for coming here today as well. We look forward to learning from you and appreciate your time.

Thank you, Madam Chair, for holding this really and genuinely important hearing, and I yield back the balance of my time.

Ms. DELAURO. I thank the gentleman.

And now it gives me great pleasure—and she said it well. You know, it is 15 months. We can do a lot of great work in 15 months, and she will continue to do that as chair of the Appropriations Committee. I would like to yield time to Congresswoman Nita Lowey.

The CHAIRWOMAN. Well, thank you so much, Madam Chair and my friend ranking member, and members on both sides of the aisle. We have been working together on critical issues for a long time.

And I love this committee. My heart is with this—my heart is with all the committee, but my special love here. And I look forward to hearing your testimony.

I just want to say I remember very clearly,—and I think my friend the chair had a similar experience. My granddaughter was visiting me a few years ago in Washington, and we were just chatting around the table with another friend. She brought another friend with her.

I didn't have the foggiest notion that this even existed, that it was as widespread. And when she said that 60 percent of the kids in her high school class, 60 percent were addicted, I said "What?" And that is when I and many of us began really aggressively going after this.

In fact, I walked into a local store, and I said, "I am going to do everything I can, sir, to put you out of business. Have a good day." [Laughter.]

The CHAIRWOMAN. True story. Wish I could be more successful in that. But I do want to thank our chair, Ranking Member Cole, thank you so much for holding this hearing today. And I want to thank—there is so much going on—for all my colleagues on the subcommittee for being here, and we are all pleased to welcome our distinguished witnesses.

To say that we are concerned is the biggest understatement because since that time, I have had roundtables in my district. I have talked to dozens, perhaps more, hundreds of kids. And when you hear now there are 26 deaths confirmed, including in my home State of New York, it is really shocking.

The dramatic use of these products among youth, which is an epidemic, is alarming. When you look at the numbers, one in four kids are using e-cigarettes, and now a new generation of Americans is hooked on nicotine.

So, as a Member of Congress with a long history of support for anti-tobacco efforts and advocacy for tough regulations on e-cigarettes, but as a mother and a grandmother, it really is so heart-breaking, in addition to being outrageous, that we are at the nexus of two public health crises, vaping-related illnesses and deaths and an epidemic among youth that really was largely avoidable.

I do remember my meeting with Dr. Gottlieb in the office with my wonderful staff, who is now on maternity leave, brought me all kinds of samples that you could buy in the mail. And frankly, I

shouldn't have been so innocent, but I said, what, tutti-frutti, all these different flavors that clearly were encouraging kids and that they could just buy in the mail was so shocking to me at the time.

So in my role as chairwoman of the House Appropriations Committee, I have consistently opposed tobacco industry efforts to weaken FDA's enforcement of the Family Smoking Prevention and Tobacco Control Act. I supported this committee's increase for the CDC's Office on Smoking and Health in fiscal year 2019, and I support a further increase in fiscal year 2020. This is particularly important now, given the current outbreak in illnesses and deaths related to e-cigarettes and other vaping products.

So I want to urge again the CDC to continue its vital laboratory research and investigatory efforts to get to the bottom of the ongoing outbreak, to update the public on the serious health risks associated with these products. In fact, I have to—I won't go into too much detail, but I was part of one of my roundtables, where I was really arguing with some of the young people there who thought, hmm, nothing wrong with it. Boy, they didn't realize now that they are addicts. But at the time, they thought nothing wrong with it.

And I just want to say that I know how important it is that CDC receive adequate funding to do the work. The advocacy community must remain vigilant in helping to communicate to the public the risks of these products, and we have to do everything that we can through legislation, outspoken—outsourcing the message wherever we can get it. But I really do thank the chair and the ranking member for having this hearing today. I think it is so very important because somehow, although we have known about this for a couple of years, the numbers keep increasing and increasing. In our public schools, private schools, wherever you go, the numbers of users keep increasing.

So thank you, thank you, thank you.

Ms. DELAURO. Thank you.

Now let me recognize Dr. Anne Schuchat, Principal Deputy Director for the Centers for Disease Control and Prevention.

I want to just say thank you for being here today and for the many, many times that you have come before us. And you have been at the forefront of a number of these public health crises, whether it is Ebola or other infectious diseases, and we are so grateful for your expertise and competence, but for your dedication and for your commitment to these issues.

Thank you so much. Your full written testimony will be entered into the hearing record. You are now recognized for 5 minutes.

Dr. SCHUCHAT. Thank you so much, Chairwoman DeLauro, Ranking Member Cole, and members of the committee. I also want to congratulate Chairwoman Lowey on her retirement and thank you for your many, many years of service to the Nation.

The CHAIRWOMAN. I will be here 15 more months. [Laughter.]

Dr. SCHUCHAT. Absolutely, and I am happy to come back, OK.

I would like to tell you today what we know and what we don't know and what we are doing about the lack of knowledge and also a bit about what we are doing about the youth epidemic of e-cigarette use. I want to make four key points.

First, since we first learned of these cases of lung injury, CDC has been working 24/7, hand-in-hand with State and local public health as well as the FDA, to try to get to the bottom of it.

Secondly, our ability to do this kind of investigation critically relies on the infrastructure of public health, including the data systems that need modernization and a trained and data savvy workforce.

Thirdly, CDC has made important recommendations for the public. Based on the investigation so far, we have recommended that people do not use vaping products that contain THC. Regardless of this investigation, e-cigarettes or vaping products should never be used by youth, young adults, or pregnant women; people should not acquire these products off the street, and they shouldn't further modify them. Adults who use e-cigarettes or vaping products because they have quit smoking cigarettes should not return to smoking cigarettes.

Fourthly, we need to address the broad epidemic of e-cigarette use among youth. What we know so far about this epidemic is that it is striking young people. More than half of the cases are under 25 years, about 70 percent are male, and new cases are being reported every day. I expect this week's numbers to grow considerably.

What we don't know, unfortunately, is the cause. We know that the most recent reports suggest that most patients report using THC-containing products or both THC-containing products and nicotine-containing products. However, because nicotine-containing products have been reported to be used either alone or in conjunction with THC-containing products, we cannot exclude the possibility that nicotine-containing products play a role.

No single product, brand, substance, or additive has been identified in all cases so far. It may be that there is one cause or that there are many problematic substances causing lung injury, and there may be complex root causes for the increases that we are seeing right now.

CDC is working vigorously with States to respond. We have dispatched our disease detectives to assist some of the State and local public health departments. We have activated our Emergency Operations Center. Our incident manager is coordinating our response.

Last Friday, we issued updated clinical guidance based on inputs from clinical experts who have been caring for these patients and the accumulated information from cases around the country. We are doing frequent calls with the public health community, clinical organizations, and the media to keep people informed.

We are working very closely with the FDA on traceback of products that people have used, and our laboratory is assisting with the clinical pathology testing and working with FDA's lab on testing of products and aerosols produced by the products.

But this outbreak has a number of challenges. The investigation includes trying to gather information about exposures to potentially illicit products, so some respondents may not be totally forthcoming. State laws vary regarding THC and cannabis use, and that can also complicate the data collection.

E-cigarettes or vaping products are part of a marketplace that is very wide and extremely diverse. A multitude of product varieties and different substances can be used with the devices. And there is the issue of counterfeiting or black market products.

Public health data collection for the response, as you have said, is relying on antiquated and fragmented systems that need modernization. The disease, unfortunately, is moving faster than our data systems, and that is a barrier to getting to quick answers.

Briefly, I want to mention the epidemic of youth use of e-cigarettes. We know that youth are much more likely than adults to use e-cigarettes and that flavors are a key part of that appeal. We have been messaging our concerns about youth use of e-cigarettes since 2013, when we got the initial data about the alarming increase from 2011 to 2012. The problem is much worse now, and we continue to consider this a great concern.

In closing, CDC is dedicated to working around the clock, together with State and locals and with the FDA, to get to the bottom of this and to keeping you updated.

I look forward to your questions.

Ms. DELAURO. Thank you very much.

Dr. Schuchat, August 1, CDC was notified by Wisconsin about a cluster of pulmonary illness among young adults that began in July. September 16, CDC activated the Emergency Operations Center. It is now exactly a month later in the outbreak investigation, but this suspected chemical exposure is ongoing.

During your career at CDC, you have been engaged in the numerous responses including H1N1, pandemic influenza, SARS, Ebola, and anthrax. How is this outbreak similar or different than others conducted by the CDC?

And if I can just mention a follow-up at this moment, what impact do you expect flu season to have on the current outbreak investigation? It is my understanding that lung injury from vaping can result in symptoms that might be misdiagnosed as the flu.

Dr. SCHUCHAT. Thank you.

I have been involved in a number of complex multi-State and also international outbreaks. This is extremely complicated and difficult. It is affecting young people. It is fatal or potentially fatal, with half of the cases requiring care in an intensive care unit.

It is affecting every State, and it is not caused by an infectious pathogen, which is our usual story. But like most of the other outbreaks, it is relying on the public health infrastructure of the Nation—State, local, and Federal—and CDC's tried and true approaches with our Emergency Operations Center and Incident Management System are helping. But as I have mentioned, the antiquated data systems are kind of handcuffing us at some point.

The issue with influenza is very important. We are right now moving into the winter season when influenza illness may be increasing, as will other respiratory viruses that are common in the winter. Last Friday, in our updated clinical guidance, we urged recommendations for evaluating individuals with respiratory symptoms to consider both lung injury associated with vaping or e-cigarettes, as well as influenza, and to treat for both, if appropriate.

Of course, a person who has lung injury or lung damage from e-cigarette or vaping product use may be vulnerable to worse com-

plications of influenza. We don't want to withhold treatment of one at the expense of the other. It is going to be a very challenging winter.

Ms. DELAURO. Last year, there was an outbreak of E. coli that sickened 62 people in the U.S. When CDC determined that the source of the outbreak was romaine lettuce, CDC delivered the clear message, "Do not eat romaine lettuce."

However, despite CDC's overall warning to the public that no one should use tobacco products, CDC's message for weeks around an outbreak that has sickened nearly 1,300 people, killed 26, has to been to "consider refraining from using e-cigarettes or vaping products that contain nicotine."

Let me just ask you why hasn't CDC's warning been more urgent? Why are we not saying don't use e-cigarettes at all until we figure out what is going on?

Dr. SCHUCHAT. Thank you.

We strive for clear, actionable communication. For this investigation, we are trying to update our recommendations frequently based on the best evidence available. And we have updated that information as more and more data has come to light about the THC-containing prefilled cartridges.

Regardless of this investigation, we want to be very clear that e-cigarettes should never be used by youth, young adults, people who are pregnant, or by adults who aren't currently using tobacco products. No tobacco product is safe, and we really want to make sure that is clear. But for the outbreak investigation, we are following the evidence and trying to make our messages as clear as possible, but still evidence-based.

Ms. DELAURO. Let me just say the current outbreak really highlights the role of CDC and the FDA working together in terms of the public health. CDC—well, FDA is a regulatory agency. What role does CDC have in providing information to FDA as it makes regulations?

Dr. SCHUCHAT. We work very closely with the FDA to share the evidence that we have. In fact, we actually collaborate on the National Youth Tobacco Survey, the results that showed that shocking increase in the e-cigarette use in high school students and middle school students. So we feel that our—as an evidence-based, data-driven agency, we want to get the best information possible available as quickly as possible to the regulators, but we don't make the regulation ourselves.

Ms. DELAURO. But just I have got 3 seconds here, in terms of do you have any sense of timing when you will make a forthright statement the way you did on "Do not eat romaine lettuce" to the public? I mean, what is the timing on that?

I understand the areas that you have carved out about youth, young adults, pregnant women. But where are we going on this?

Dr. SCHUCHAT. We follow the evidence, and we update it as there is more evidence. For this investigation, we have updated to say do not use e-cigarette or vaping products containing THC. Do not buy any products off the street or from informal sources.

But for the e-cigarette use in general, we have focused on the populations where the evidence is very clear in terms of the devel-

oping brain up through age 25. That is why we focus on young adults as well as youth and on pregnant women.

In terms of adults who are trying to quit smoking, there is mixed evidence now, and none of the products are approved as cessation devices. But that is an area where we haven't said don't do that yet, and that is basically following the evidence as it emerges.

Ms. DELAURO. Let me be clear. The THC, while it is a factor, it is not the only factor. Nicotine is a factor. So that the notion that if you remove this THC, then everything is hunky-dory, it is all right to move forward, that is not what you have said. You said that it plays a very—nicotine plays a very, very strong role in what the problems are.

Dr. SCHUCHAT. Well, in terms of the youth use of e-cigarettes, it is a huge role. In terms of the epidemic of lung injury, we don't know yet.

Ms. DELAURO. Thank you. Mr. Cole.

Mr. COLE. Thank you very much, Madam Chair.

And thank you very much for your testimony. It is very helpful. The speed at which this has evolved reminds me sometime of the opioid crisis or things like that where we have seen products have consequences we didn't really initially understand when they were released into the marketplace, and particularly the youth addiction.

You mentioned in your testimony some of the various factors that make this so difficult to analyze compared to an infectious disease. I would like you to elaborate on that a little bit, particularly in two areas.

One, in terms of the difficulty of investigating when you have illicit use in many of these cases of THC. And second, what, if anything, does the difference—and you have touched on this a little bit in your testimony—the difference in marijuana laws at the State level, which we have had an explosion of legalization, obviously, in the last few years. How does that play into both your investigation and the potential spread of the delirious consequences of vaping here?

Dr. SCHUCHAT. Some of the complications of the investigation involve the substances that are being used. The e-cigarette or vaping products have a variety of components. They are not necessarily labeled fully, and there probably are counterfeit and black market influences such that even if there were labels, they wouldn't be telling you everything that is inside.

In terms of the interviews with patients who are very, very ill, they may be too sick to tell you. They may have had many different products that they used. I think some of the interviews suggest like 40 different products that people report having used. There may be little product left to test, and it may not be the product. It might be the device that the product is being used with or the aerosol that the product produces. So the laboratories are busily testing a variety of things.

There may be more than one outbreak. This outbreak that has nationally got our attention may be a lot of local sources of problematic substances.

In terms of the State laws, obviously, we are working very closely with the States. We are working very closely with the FDA and the DEA on the traceback investigations and the particular substances.

In terms of interviewees being forthcoming, of course, there are some issues about if they will be forthcoming about an illicit product. But I think it is also worth remembering that a lot of kids don't want to tell their parents that they are using any kind of tobacco product. That, of course, it is illegal in most States, depending on the age. So there is a challenge for the clinicians and the State investigators to gain trust and get real histories from people.

So this is complicated, fast-moving, and challenging, but it is critical. And it is exactly why CDC exists, to stop this kind of outbreak before we have more deaths.

Mr. COLE. Obviously, you know, vaping is done internationally, not just here. What are—your contacts in other countries with other healthcare organizations, are they experiencing the same sorts of things that we are? Are they somehow different? Is there a better regulatory scheme that you have seen out there than we have?

Dr. SCHUCHAT. The international contacts that we have do not reveal a large problem in other countries. There are individual reports being investigated, but nothing right now like what we have seen.

The regulatory environment is different. The smoking environment is different. Both the legal and illegal markets are very profit-oriented. And the environment for smoking cessation is quite different country to country.

So sometimes an outbreak, a food-borne outbreak might be international. This one doesn't yet seem to have international scope.

Again, you mentioned the opioid epidemic. We are experiencing a very different opioid epidemic than Europe, but we had a backdrop of a huge amount of prescription opioid use. I do think it is possible that the epidemic of nicotine-containing e-cigarettes has created a generation that is almost addicted to vaping, whatever the product is.

And now we have devices that are so small that can be used discreetly inside the classroom with no odor and making it very hard to stop that behavior, whatever is in the cartridge.

Mr. COLE. Well, again, I know we have put a lot on your plate here, and I, frankly, appreciate the quality and the speed with which you are working. But I would hope that you look at this internationally as well, just to see if there are lessons to be learned from other countries and to see if there are some unique factors, obviously, in the problem we have in this country that truly are a product of either the manner in which we regulate or the diversity of regulatory schemes that we have across multiple State lines.

Dr. SCHUCHAT. Thank you. Actually just last week formed an international team as part of our incident management and are connected with the WHO and with European and Canadian colleagues.

Mr. COLE. Thank you. Thank you, Madam Chair.

Ms. DELAURO. Congresswoman Lowey.

The CHAIRWOMAN. Thank you. And I want to follow up on the wise comments of my good friend Mr. Cole.

Thank you. I was just complimenting you. [Laughter.]

Mr. COLE. I know. You are being really nice in your last 15 months.

The CHAIRWOMAN. Oh, you are always my good friend. But I think that is a very important point that I want to follow up on.

E-cigarettes have been marketed as an alternative or off-ramp for existing adult smokers seeking to stop using combustible cigarettes. Several of us, as you have heard, are concerned that this is a false narrative that only encourages tobacco use and that both adults and young people will, for lack of a better word, graduate to combustible cigarettes if they use e-cigarettes.

So, number one, I would be interested in your thoughts on this. And I know CDC has been working on the stop smoking for a long time, but what more can CDC do and what help is needed from Congress to help current e-cigarette users and smokers just quit? I will leave it at that.

Dr. SCHUCHAT. CDC acknowledges that e-cigarettes are used by some adult smokers to help them quit, and there is emerging data about whether there is strong enough evidence there for that to be recommended, although none of them have gotten approval from FDA as a cessation device. But we are very, very troubled by the marketing to youth and the flavors and the stealth approach to get teens hooked on nicotine-containing e-cigarettes with very high levels of nicotine and sort of a life of addiction, and we share the concern about whether they will move on to combustibles and the dangers that nicotine has on the developing brain in general.

In terms of the support from the committee and from Congress, we really were very appreciative of the proposed increase in the tobacco line. Our State and local colleagues tell us that they are stretched very thin in terms of addressing the epidemic of adolescent tobacco use while continuing the other approaches that are so critical as part of a comprehensive tobacco control project. And we are also very appreciative of the proposed increase for the data systems, which we think is just vital.

What we know right now about how to help young people quit tobacco or e-cigarette use is not as much as what we know about adults. But we think that in addition to the individual counseling and cessation efforts, the environmental or population-based activities are very important. Tobacco-free indoor areas, restrictions on where the products can be sold and so forth, all can reinforce youth not being able to go back to nicotine use if they stop.

So I think that there is a lot of work to be done, and unfortunately, while there is a strong evidence base of how to reduce tobacco use, we have a growing problem of a new generation that we need to apply those tools to. So we do know what works, but we have to apply it on a larger scale than we did.

The CHAIRWOMAN. Well, I thank you so much. And just closing, I wonder what kind of research is being done on just that? If more information is coming out about THC, and kids are getting a little worried because they see their friends coughing, coughing, coughing, getting sick, is there any movement to using e-cigs without the THC because you don't want them to be addicted to nicotine with or without?

I just wonder if it is too early or what is happening out there?

Dr. SCHUCHAT. What I would say is that it is hard for us to keep up with the behavior changes. We know from the National Youth Tobacco Survey that among e-cigarette users of nicotine-containing

e-cigarettes, use of THC is very common. About a third of them also use THC in their devices.

But our annual survey barely is keeping up with the market changes and the product introductions. We do sales monitoring to keep up with that. But I think we have to really pick up our pace to understand what the practices are in order to intervene.

So there is just a lot to do right now. And again, it is kind of shocking how large the numbers are of teens now that are reporting current use, and much of that current use is frequent use.

The CHAIRWOMAN. Well, I have 2 seconds left, or minutes, whatever this is. So I just want to thank you, and this is what is beginning to worry me. So if they say, OK, I don't have any of that stuff in there, but they are getting hooked on nicotine.

Dr. SCHUCHAT. Yes.

The CHAIRWOMAN. Just when we were making product—

Dr. SCHUCHAT. Progress, yes.

The CHAIRWOMAN. "Progress" is the word I was looking for. So I thank you for your work, and we have to, obviously, invest more and just stop it, no smoking. Thank you. Don't get started is more the word.

Ms. DELAURO. Congressman Moolenaar.

Mr. MOOLENAAR. Thank you, Madam Chair.

Dr. Schuchat, nice to see you again, and thank you for being here and for your testimony.

You had mentioned the challenge of the data collection and reporting systems being antiquated and fragmented. Could you speak to that a little bit and also what you feel Congress should be doing to help address that in terms of investment in CDC's data collection and reporting systems? Also kind of where you see data standardizations and interoperability being a hindrance to some of these investigations.

Dr. SCHUCHAT. Yes, thank you.

The public health data system has a lot of challenges right now. If you look at what has happened in healthcare information technology, we have really seen a dramatic improvement in electronic medical records across the country and in better use of technology to improve health. The public health system hasn't benefited from that. The systems that we rely on are different in many States. Many States are still using paper and pen or faxes.

When we have a multi-State challenge like this, there are different approaches in each State, and we try to get consistency, and we are not connected with the healthcare system records. So when you are trying to review a complex medical chart about a difficult lung injury, people are faxing, you know, hundreds of pages of medical records to the health department for that review. We are just not using technology effectively.

CDC has been working on a strategy and a plan for how to catch up, and we are working with the public and private sector on that strategy, but we really think that the public needs the public health system to be in better shape than it is, and it is definitely slowing down our response.

We think that interoperability and data standards are critical. So is innovation, and so is recognizing that we are not trying to build one, big monolithic system that can crash. We want to be investing

in a smarter way that will be adaptive over time, but that will get us information earlier and with a workforce that can actually use data to predict problems rather than react on it late.

Mr. MOOLENAAR. Do you have a timeline on when you think that plan would be completed, and I am sure with your support, you know, I think it would be fascinating for this committee to hear that once it is ready.

Dr. SCHUCHAT. And we would be happy to share with you where we are with it and then more details about where we want to go.

Mr. MOOLENAAR. Thank you.

Ms. DELAURO. To my colleague, if you yield for a second, that is one of the reasons why we have put in the \$100,000,000 because we found—and this turned up. In most health crises, we leave our States at—really at risk because we don't have a very substantial public health infrastructure nationwide. Again, which is one of the reasons why we buttressed that up in our bill.

Mr. MOOLENAAR. Thank you.

I wondered if you could also talk a little bit about—because, you know, I have been reading different articles, and I am still trying to get a picture for what is actually happening here. I am assuming the lung injury is pretty similar in each case, or are there different types of lung injuries and infections, or how would you characterize what we are seeing?

Dr. SCHUCHAT. Yes, we are still gathering the data. The clinical symptoms are fairly similar. The people develop shortness of breath, cough, sometimes chest pain, sometimes fever, and about three-fourths of them have gastrointestinal symptoms around the same time—nausea, vomiting, stomach pains.

Many progress to life-threatening difficulty breathing, where half of them are admitted to intensive care units, and about 20 percent need to be on a mechanical ventilator. The x-rays look like what we call bilateral, both sides of the lungs, diffuse infiltrate. That is very nonspecific.

The extra testing that is done doesn't show an infection, which would be common. The imaging, the x-ray or chest CT, shows many different patterns that are diffuse. But what we are trying to do right now is look at pathology, look at the clinical specimens, and there are a couple different patterns that are being seen.

I think it is too soon for us to know whether this is one substance causing a chemical reaction or multiple different kinds of substances in individual cases. And so that is why I say it may be multiple outbreaks on this as common backdrop of the vaping or e-cigarette product use.

Mr. MOOLENAAR. And I recognize the challenge when you have illicit drugs being used, and you aren't sure what someone is putting into the mix. In cases where these are being sold legally, you had mentioned sometimes there is not full labeling or, you know, that is there is a mystery there. Can you speak to that?

Dr. SCHUCHAT. Yes. I think that, State by State regulation of THC, or marijuana, will vary how the products are required to be tested and labeled. The e-cigarette products aren't right now approved by FDA. So there are really no requirements of what they have to say. So it is kind of hard to know what is in them or what is produced by them, at least that is my understanding.

And what we do know is that the aerosol that a nicotine-containing e-cigarette can have will produce a lot of different compounds. Not as many as combustible cigarettes, but there can be organic volatile compounds, heavy metals like lead. You know, there is a device that is involved heated to high temperatures, what they call ultrafine particles, which has lung specialists worried because that is kind of like silica and silicosis.

Then what we see with—especially young people using e-cigarettes—is they are using them all day. It is not like the old days where you had to go, you know, before school or after school they were smoking cigarettes. They are using them in class, in the bathrooms, all through the day. And so they are getting enormous amounts of that aerosol exposure. And then, similarly, we hear that the THC use is often quite frequent.

So I think that the damage that the variety of substances might have on the lungs could be diverse, and then what we are really worried about with the outbreak is adulterants or cutting agents or solvents being used to increase the profit. Adding oil or other chemicals to the THC-containing cartridges that will make more of a product for the dealer, but really it is uncharted territory what that does when it is heated to high temperatures and is inhaled.

Mr. MOOLENAAR. OK. And then, finally, we had the NIH Director Collins and a team from NIH talking about the current scheduling of marijuana and the effect that that has on the research. Do you find—do you feel that it would be helpful to you to have additional research on THC in this area, and is the scheduling of that interfering with some of that research?

Dr. SCHUCHAT. Well, we don't have specific funding for the THC work right now. So that might be more of a barrier for us than the scheduling. But, I share Dr. Collins' view that a lot more research is needed and that there are many questions that it would be helpful to understand.

So the scheduling may have less impact on us because essentially in our National Youth Tobacco Survey, we have a couple questions, and in our Behavioral Risk Factor Survey, we have a couple questions. But we are not investing in research right now on marijuana or THC.

Mr. MOOLENAAR. OK. Thank you very much.

And thank you, Madam Chair.

Ms. DELAURO. Congresswoman Roybal-Allard.

Ms. ROYBAL-ALLARD. Dr. Schuchat, thank you for being here today and for everything that the CDC is doing to identify and address the causes of lung illness and death associated with vaping.

I think up to this point it has been well established that we are in a crisis situation, and so I would like to focus my questions on the resources that CDC is going to need in order to adequately address this crisis. So, first of all, I would like to have you maybe elaborate on the strategies that CDC is employing to address youth vaping behaviors, and what resources do you need to be successful in this?

Dr. SCHUCHAT. Yes, thank you.

We carry out much of our work through funding of the State and local tobacco control efforts through the public health departments, and they are stretched thin right now. They say about half, 50 per-

cent or so of their resources are going towards youth issues, and that is inadequate in terms of the growing problem in youth and that we haven't finished the job in adults yet.

The approaches that are taken are a comprehensive program, which involves a variety of strategies. Mass media, which can include school-based efforts as long as they are not industry-sponsored school-based efforts. But also things like our TIPS campaign or what the Truth Initiative is doing or FDA is doing targeted at youth.

A second area is around price controls, which is certainly done by the States, not by us. A third area is smoke-free policies, and that that really can play a role in terms of reducing secondhand smoke or secondhand aerosol exposures, but also reinforcing quitting once people have quit and help people not start.

So those are the types of approaches, and I think a key thing that CDC wants to do is monitor the data. Each State is tracking the youth tobacco use as well as adult use through other means, and having that data accessible quickly and being able to adapt it to the newer threat.

So those are the kinds of things we do with the resources. But of course, in this response, we are also doing a rapid-fire incident management, multi-State investigation, which involves epidemiology and laboratory and communication and policy, the international team I mentioned, as well as data systems work.

So I think we are working on a lot of fronts right now, but with an increase in resources for tobacco, we would very much want the States to be able to focus on expanding their youth activities.

Ms. ROYBAL-ALLARD. It was mentioned earlier, after years of relatively flat funding, the House fiscal year 2020 Labor, HHS bill included a \$40,000,000 increase for CDC's Office of Smoking and Health. Unfortunately, the Senate bill level funds OSH at \$210,000,000. If the Senate level were to be approved, what activities would CDC not be able to undertake to stem this youth epidemic?

Dr. SCHUCHAT. Yes, essentially, the States would be having to decide between children and adults, and that is not really a great option. We know that of adult smokers, 70 percent or more want to quit, and their access to cessation products and quitlines is really important. And that is a key thing that the States do.

And we know that new young people taking up e-cigarette use is possibly leading to a life of addiction and harming the developing brain and increasing their risk for addiction to other substances. So it is really a terrible choice.

But I think you can see in the numbers between the acute investigation and the rising youth use of e-cigarettes that there is a growing problem, and diminished resources would not help.

Ms. ROYBAL-ALLARD. OK. Can you tell how much of the current OSH budget is dedicating to addressing the e-cigarette epidemic, and is that funding being drawn from resources that would have otherwise been used to reduce the use of cigarettes and other tobacco products?

Dr. SCHUCHAT. The States tell us about half is going towards youth, that is pretty much e-cigarette targeted right now, and yes,

that is drawing from—the resources available for adults in terms of the quitlines and cessation access and so forth.

So it is, and having the mass media campaigns can be quite expensive and having ones sort of targeted towards where youth get their information is a different approach. So there is quite a lot to do right now.

Ms. ROYBAL-ALLARD. So my understanding is a large part of the burden is falling onto the States themselves to do this?

Dr. SCHUCHAT. That is right. We—

Ms. ROYBAL-ALLARD. They are not adequate—they don't have the adequate amount of resources?

Dr. SCHUCHAT. That is right, yes. That is right. Most of our resources go to the States directly or indirectly. And they are stretched thin now. Some of their tobacco settlement resources are gone, are going to the general fund, not towards their tobacco control program.

So with this increase, we thought we were making progress. Adult smoking was down, and even e-cigarette use was down, and then the last couple years, it is starting to skyrocket. So the resources are stretched thin, and we need to really redouble our efforts to get the trends to go back down.

Ms. ROYBAL-ALLARD. Thank you.

Ms. DELAURO. Congresswoman Herrera Beutler.

Ms. HERRERA BEUTLER. Thank you, Madam Chair.

Okay. So I think our goal is to do the hearing, at least the way I see it, is we want ideas that are going to help us end not just the current outbreak, but address the underlying situation, right? And we are just gathering information.

I wanted to really quickly read a couple things that are now updated on the CDC website for our constituents to read. "Most patients report a history of using THC-containing products." There is another line, "The latest findings suggest products containing THC play a role in the outbreak."

Next line, "While this investigation is ongoing, CDC recommends that you consider refraining from using e-cigarettes or vaping products, particularly those containing THC." Another line, "Anyone who uses e-cigarettes or vaping products should not buy these products from informal sources or off the street," right?

And then I guess my next thought is, you know, let us be very clear, "No teen use of marijuana is legal anywhere," right? There is no regulated market for marijuana use for teenagers recreationally. And THC is still federally illegal everywhere. So we all know that. And it is illegal in 39 States.

You know, no THC vapor is legal for 8th, 9th, 10th, 11th, 12th grade use. Yet CDC, your Youth Behavioral Risk Survey or surveillance system tells us almost 20 percent of youth have used marijuana in the last 30 days. And then according to Federal data, the percentage of those kids vaping marijuana instead of smoking it or ingesting it is also going up.

So this is the pool of kids I am most worried about, and yes, I am worried about adults who want to get off of smoking, absolutely. But when you are looking at investment and how do we put our money in, you know, stopping that expense on the backend, in

lives and in dollars, we need to get at them now, especially as this is exploding.

You know, this has taken the lives of at least 26 people. Where do we—I was so concerned to hear that there is not research with regard to THC or marijuana use, especially the impacts of it, at CDC. What do we need to do to help you get that research?

Dr. SCHUCHAT. Yes, thank you.

I do think there is general agreement that youth should not be using THC or nicotine, and the scope of the problem is getting worse. The marijuana rates are probably kind of flat, but the exposure to these vaping devices that allow for very discreet use may be changing the dynamic a little bit.

CDC works really closely with both NIH and FDA on the tobacco issues and also on the substance issues, and so the research portfolio that NIH has, we may be very support of. Exactly what research we are doing or would do with resources would need to be complementary. It would be less of the basic science kinds of lung pathology that they would be doing or addiction research that they do in NIDA and probably more of the behavioral change, marketing strategies that would help the State health departments get their challenges met. The State health departments really want more help with marijuana as well as with nicotine.

Ms. HERRERA BEUTLER. And is that something then—so addressing the behavioral or the way to communicate with young people, I am just going to break it down.

Dr. SCHUCHAT. Right.

Ms. HERRERA BEUTLER. That is where—that would be more in your wheelhouse, yet you guys don't have necessarily any proposals for that? You are not requesting that? Or is that something—

Dr. SCHUCHAT. We don't have a marijuana funding line through your appropriations. We have broader lines that we use to support the core work that we do, but we are not funded to do research on marijuana.

Ms. HERRERA BEUTLER. And so we would have to specify that?

Dr. SCHUCHAT. I think so, yes. But we could probably get you more informed information after the hearing, then, about the particulars.

Ms. HERRERA BEUTLER. I would like to have it, just because everybody keeps saying it is a problem, it is growing. And yet no one can answer this question, and you are the CDC. That baffles me.

And my State has legalized it, a number of States have, for recreational use. And yet I don't even hear, hey, you guys aren't funding what we are asking you to do here. You're saying, well, we haven't necessarily really even put it in our ask.

And I don't blame you. I'm just saying that tells me we need to get this—we need—I am ready to help step up and get you what you need. But we—you guys are the—you are the doctors and the researchers, right? We need your help.

Dr. SCHUCHAT. Yes, and we do hear from the States across the country that more understanding of the trends that are going on and the risks and benefits and the best approaches to the regulatory requirements that they have would be helpful. So we get a lot of requests from State health departments and their organizations.

Ms. HERRERA BEUTLER. Well, now I have a request of you. I would love to have someone in your office come maybe meet with us on how we could help facilitate that.

Dr. SCHUCHAT. OK, thank you.

Ms. HERRERA BEUTLER. Thank you.

Ms. DELAURO. Congresswoman Clark.

Ms. CLARK. Thank you, Madam Chairwoman.

Thank you, Dr. Schuchat, for being with us today.

I had a question for you on the National Youth Tobacco Survey that showed a decline in e-cigarettes and then an increase in 2017–2018. Do we know some of the reasons behind that increase?

Dr. SCHUCHAT. Yes, the timing of the increase tracks pretty well with what we call the “fourth-generation e-cigarette device,” and Juul is the sort of poster child for that. And those devices use nicotine salts, which are not as harsh as plain, old nicotine, and so the taste is more acceptable to young people first trying it.

They had higher concentrations of available nicotine, and the device is quite small and can be put in your pocket or used discreetly so that kids could use them in school. Parents wouldn’t know what they were. They look like USBs or highlighters and so forth.

And so the huge uptake from 2017 to 2018, and then again in the preliminary results for 2019, really tracks with the market share of Juul just skyrocketing during that period.

Ms. CLARK. And do we have good data on the use of e-cigarettes and giving up smoking? Do we have data on the efficacy of that?

Dr. SCHUCHAT. No. There is emerging data, but there have just been three randomized control trials in terms of a cessation approach, and the data from those trials is mixed.

The evidence basis, as Chair DeLauro mentioned, from the National Academy of Medicine reviews that it is sort of mixed evidence at this point and not yet recommended as a cessation approach. And none of the e-cigarettes have FDA approval to be used for cessation.

There are seven different FDA-approved cessation tools that have gone through full review. So there is mixed data there in the U.S. We are a data-driven, evidence-based organization, and we love to see data. But at this point, that data hasn’t been pulled together.

Ms. CLARK. You know, it is alarming to hear you talk about these ultrafine particles, that even though it may be less toxins than in combustible cigarettes. But how long—if you can answer such a general question, how long does it take for us to see those kind of what we saw with asbestos showing up in lung disease from usage like this? Or do we have any idea?

Dr. SCHUCHAT. Yes, there is so much research that is needed. I think that, actually, CDC’s National Institute for Occupational Safety and Health has done a lot of work on lung diseases, including silicosis and asbestosis and so forth and, in fact, the popcorn lung that we were hearing about before with the same chemical that is in some of these flavors.

We are used to studying these things occupationally because of the high doses that people used to get as workers when they weren’t using respiratory protection, but we don’t really have the same kind of science yet on young people doing 24/7 vaping of high doses of fine particles into the depths of their lungs.

And I think this outbreak of lung injury is showing us that some damage can happen really fast, depending on what the substance is. In terms of the nicotine e-cigarette devices and the harms they may have over time, I don't think we have that data yet.

Ms. CLARK. And one of my concerns, using a small focus group of my teenage sons and their friends, is that there is a growing—well, you know, if you are not using THC, this is still perfectly fine. So we need to get those education pieces out, and you have talked a lot about the infrastructure. And I know you have a report coming, but can you give us some specific supports that we could give you around educating the public, where sort of we are breaking down in the public health infrastructure on this?

Dr. SCHUCHAT. Yes. I think the teens definitely have that impression that there is no problem. It is not a cigarette. They don't recognize there is nicotine. They don't often have any idea that it is harmful.

Ms. CLARK. And the salts have higher levels of nicotine?

Dr. SCHUCHAT. Yes, the salts can make a higher level available. One pod of Juul is like a full pack, it is like 20 cigarettes. And people, may go through a pod a day or every other day, and as I said, they can be using them in class. Whenever the teacher turns her back or his back, they are using these products. And slip it in your pocket, and you have no idea it is going on. The level of use may be quite high. So I think there is a lot of work to do.

Now the FDA has a campaign called "The Real Cost," which is really aimed at youth, and the Truth Initiative has a youth-targeted campaign. But I think there is a lot more we need to do. We know that some of the companies have gotten youth influencers and very, very sophisticated youth-targeted advertising to get people hooked, and we have to counter that.

Ms. CLARK. Thank you.

Ms. DELAURO. Congresswoman Lee.

Ms. LEE. Thank you, Madam Chairman. Thank you for this very important hearing. I apologize for being late. So if I ask—these questions are redundant, just say so, and I will move on.

But this is such an important issue that so many communities have been grappling with, and so I just wanted to ask just a couple of really just basic, cut through the smoke questions. In terms of just e-cigarettes, are they safe to be used right now?

Dr. SCHUCHAT. We don't think there is any safe tobacco product. So e-cigarettes containing nicotine should never be used by youth, young adults, or pregnant women, or by adults who aren't previously tobacco users. The developing brain through age 25 can be harmed by nicotine, and the individuals using nicotine at young ages may have a higher risk of progressing to combustibles and also to addiction to other substances.

So there are populations where nicotine-containing e-cigarettes are just absolute noes. But in general, we don't think there is any safe tobacco product.

Ms. LEE. Well, if they are not safe, then why is there not a complete ban until we figure out what is causing these negative health outcomes?

Dr. SCHUCHAT. Well, the CDC doesn't have the regulatory role and—

Ms. LEE. But you can recommend.

Dr. SCHUCHAT. Right. That is where what we have said is that there are groups that should never be using e-cigarettes, and those are, you know, youth, young adults up to age 25, pregnant women.

There is a lot of debate out there about adults who want to use e-cigarettes as a “safer” alternative to cigarettes. We are worried that a whole generation is starting e-cigarette use that was never going to go on to using cigarettes, and we don’t want, an off-ramp for adults to be an on-ramp for kids.

Ms. LEE. Sure.

Dr. SCHUCHAT. And if there is, sufficient data for them to be used for cessation, that could go through the process for approval.

Ms. LEE. Yes, I understand that, and I am happy that you all are raising the alarm. But I don’t see any policy recommendation coming to us saying the Congress should ban the use of e-cigarettes for the following reasons.

Dr. SCHUCHAT. Yes. So, again, we are not the regulatory body, but—

Ms. LEE. The recommendations—

Dr. SCHUCHAT. Yes, right. But the—

Ms. LEE [continuing]. Based on the data that you have right now?

Dr. SCHUCHAT. Right. And so, based on the data, the administration has proposed to enforce the regulatory authorities they have in terms of non-tobacco flavored e-cigarettes. None of the products are considered legal or authorized yet, but that hasn’t been enforced, and they are proposing to enforce that with—

Ms. LEE. But this has been going on for a long time.

Dr. SCHUCHAT. Absolutely, yes.

Ms. LEE. So it is time for you all to speak out and say something, that they should be banned for the list of reasons you just enunciated.

Dr. SCHUCHAT. Yes, and we have been saying, you know, young adults, teens, pregnant women should not use e-cigarettes and adults who haven’t—

Ms. LEE. I understand that, but I am just saying I believe that this does not take you out of your lane if you make a recommendation, a public health recommendation that we should establish a policy to ban them.

Dr. SCHUCHAT. Right. Yes, and so I would just keep saying that no tobacco product is safe. And the more we can get people not to use these, the better.

Ms. LEE. But it is not working.

Dr. SCHUCHAT. Yes, I agree with you.

Ms. LEE. Thank you very much. I yield the balance of my time.

Ms. DELAURO. Let me just say one point. The FDA at the moment has the authority. They have refused, both in the last administration and this administration, not to exercise that authority for a premarket review, which would make a determination as to the safety of the product.

CDC—we had the conversation before—recommendations, I concur with my colleague Congresswoman Lee, needs to be maybe heightened, strengthened, et cetera, to provide a recommendation

that tells them that until we have the data, the information is let us get the product off the market.

Dr. HARRIS.

Mr. HARRIS. Thank you very much, and I apologize I missed your testimony before. But we have another committee I was in.

And thank you, Doctor, for being here. I have a couple of questions that really revolve first around the lung injury issue, and one thing that came to mind is that my understanding is that in the UK, as you know, they believe that access to vaping actually helps in decreasing the use of combustible tobacco products. And it has been around a while there. Have they seen the same issue in the UK?

I mean, they have a nationalized health system. They should have centralized data collection. In their system, it actually should be much easier to detect this early. What is the UK experience?

Dr. SCHUCHAT. Our conversations with the UK do not reveal the lung injury outbreak presentations. However, their products are different than ours. My understanding is that the e-cigarettes in the UK are limited to a 20-milligram level, and ours are at a much higher level currently with the latest generation of nicotine salts.

Mr. HARRIS. And what about the use of THC-containing compounds in the UK?

Dr. SCHUCHAT. That, I am not familiar with, but we could try to get you that later.

Mr. HARRIS. But my understanding is that on Friday, the indication was that there is the belief that this is linked to the use of THC-containing substances?

Dr. SCHUCHAT. The——

Mr. HARRIS. Not the level of nicotine. It is not whether it is——

Dr. SCHUCHAT. Right. The latest lung injury outbreak data in the U.S. suggests that the vast majority have used THC. A lot of them also have used nicotine-containing, and about 13 percent of cases in the U.S. report only having used nicotine-containing devices.

Mr. HARRIS. Right. In fact, in your testimony, I think you said that one-third of youth who use, who vape actually use THC-containing substances?

Dr. SCHUCHAT. One-third of youth who use nicotine-containing e-cigarettes also use THC in their devices.

Mr. HARRIS. So, and how—what percent of youth are using nicotine devices?

Dr. SCHUCHAT. The latest, the preliminary data for this year is that it is more than a quarter——

Mr. HARRIS. More than a quarter——

Dr. SCHUCHAT [continuing]. Of current use. Current use.

Mr. HARRIS. And of those, so a third of those actually are using marijuana derivatives in their—I mean, that is how widespread the use of these marijuana derivatives are among our youth?

Dr. SCHUCHAT. Based on the data that we have.

Mr. HARRIS. Wow. So when we are told that it is OK to make, you know, recreational marijuana legal because, don't worry, it is not going to—we are not going to let children use it. The indication is, just like with e-cigarettes, children are using it?

Dr. SCHUCHAT. We don't have a great track record of keeping things away from children.

Mr. HARRIS. Away from children. And in fact, it appears that it is actually killing our children, in some cases, right? Because some people die of the lung injury. They are rare, but they do.

Dr. SCHUCHAT. Yes. We have had more than two dozen deaths so far, and we continue to hear about new deaths.

Mr. HARRIS. Right. So, look, I agree. Because one of your—one of your conclusions, actually, we probably ought to study the use of marijuana a little bit more before we go willy-nilly and make it available recreationally throughout the country, and I would say do you think this is one instance where, in fact, the unbridled and, according to Federal law, illegal use of marijuana for recreational purposes—because I am assuming that people who vape, the youth who vape are not doing it for medical reasons.

Is that what you are finding, or are you looking into that? Because there is a big discussion about medical versus recreational. Well, these 8 percent or 9 percent, are they using it because they have, you know, the usual indications that people claim for medical marijuana, or are they just using it recreationally? What is your feeling, doc?

Dr. SCHUCHAT. Yes. We don't have data. There is a lot of anecdote. But one thing I would say is that there is a lot of debate out there about whether legal status makes things better or worse in the States because some of our concerns right now are about the counterfeit and black market, whether the substances that are in products that are completely unregulated by the States are riskier than the products that are regulated by the States.

I don't think we have good data either way, but that is a discussion that is happening.

Mr. HARRIS. So are States regulating the THC-containing vaping compounds?

Dr. SCHUCHAT. Where it is legal, they inspect the dispensaries. It is every State has to set up their own plan on how they are going to do the regulation.

Mr. HARRIS. So is the feeling that the States have gone ahead, basically approving these THC-containing substances through regulation when they were basically unhealthy? They basically didn't have the scientific information about whether this was safe, but they were approving these compounds?

Is that right? I mean, they were legally sold. Is that what you are saying? They were legally sold. They ended up hurting our children, and these are when the States claim that don't worry, it is all safe. You know, we will regulate it. We don't have the knowledge to know what is safe and what isn't, do we?

Dr. SCHUCHAT. Yes, let me clarify. For the lung injury outbreak, while the vast majority report using THC-containing prefilled cartridges, they report getting them from informal sources or off the street, not necessarily from licensed dispensaries.

Mr. HARRIS. Even in States that have legal—

Dr. SCHUCHAT. Yes, so far, that is what we found.

Mr. HARRIS. Thank you. Thank you—

Dr. SCHUCHAT. But we are still gathering data.

Mr. HARRIS. Thank you, Doctor.

Ms. DELAURO. Just a point, and I would share it with my colleagues. This is about UK, and I think we need more information

there, about this estimate that 95 percent—that e-cigarettes are 95 percent safer than cigarettes first gained prominence, that was in 2015.

But there are the claim has very serious limitations. It is an educated guess among the small group of contributors, not based on thorough evidence or scientific risk analysis. I think the whole issue of what is out there and risk analysis and the whole issue of scientific data is critical to this debate.

Mr. Pocan.

Mr. POCAN. Thank you, Madam Chair.

And thank you very much for being here, and I, like Ms. Lee, apologize for not being here for the testimony. I have three hearings at the exact same time, and the one I went to earlier was about our congressional schedules. [Laughter.]

Mr. POCAN. So we are trying to fix that—and modernization. So kind of ironic, but I thought I would mention that.

To the very last point you said, I think you have made a very strong case for why we want to have legal regulation of marijuana. We already have it in many States. The problem is, in fact, in my hometown of Kenosha, Wisconsin, was one of the national cases, the two kids—and by kids, they were early 20s—who were retrofitting these devices for marijuana.

And that is the problem. It is people, because we don't have proper regulation in Wisconsin because we are going to apparently be one of the last States to do any kind of legalizing and having regulation around marijuana, that is what is killing people.

And so I think a strong case is made by our colleague from Maryland about why we should actually have legal marijuana everywhere because that way, we can have the proper regulation on it. But specifically, I missed the one part. I know you said since the moment you heard about what was going on, CDC, you have been working on this 24 hours a day.

When did you start working on this? Just I don't know that.

Dr. SCHUCHAT. Yes, we were first alerted about a small cluster in Wisconsin on August 1st.

Mr. POCAN. Okay.

Dr. SCHUCHAT. And we learned soon thereafter about what sounded like similar cases in Illinois. Those two States started to collaborate and issued an alert for other States. And by mid-August, we had engaged in a multi-State investigation and dispatched people to Wisconsin and to Illinois to assist them in their investigation and instituted a coordinated response.

We have ratcheted it up and now have had more than 200 CDC staff involved in the response so far, but every State health department is working vigorously on this.

Mr. POCAN. And thank you. And I think, you know, that was right on the State line, that particular case we are talking about. So I think it had a little overlap in both of those areas.

You know, this is one, I was trying to find an article I read earlier today. But you know, the FDA for 10 years punted, did nothing in this area. And the chairwoman of this committee, actually, Mrs. Lowey was one of the first people every time we had this issue up talked about what she was hearing from her grandchildren. And

you know, hearing about her great-grandchildren, but the stories about what was going on and really put it more in our awareness.

And one of the issues that I have been surprised, and I don't know if this is something you can take on since the FDA apparently is not, but people are getting around the law and advertising these products. I have had constituents actually send me an ad, and honestly, it was geared towards a high school crowd. It was not geared towards people who are watching Downton Abbey.

It was, you know, people worrying about "downtown abbey" maybe, right? It is a little different sort of audience. And they are really circumventing, I think, what both policymakers and agencies always tried to stop in this area. Are you going to be able to look at that issue at all? I know there is a bill introduced around this, but I think this is one of the problems.

Dr. SCHUCHAT. Yes. We don't take the enforcement actions around advertising to youth, but we do study what is out there. And I think you are absolutely right that there have been a lot of clear youth-targeted strategies to get people hooked on e-cigarettes, whether it is social influencers or digital campaigns that don't have the name of a company on them.

Looking back, that is what you can find. And they are clearly not for that middle-aged smoker who is trying to quit, but really for a teen or a tween who doesn't even know what is in the e-cigarettes.

Mr. POCAN. And we know that, clearly, from the flavors as well and things like that. So also in this article, it was interesting, and they said there are some specific things that are actually worse than cigarette smoking to a body because of how it comes in. Can you address—have you looked at some of that? Because this article talked specifically about the intake through vaping that actually is more likely to cause disease and addiction.

Dr. SCHUCHAT. Yes. The latest generation of e-cigarette devices use nicotine salts, and those are less harsh. So they are more palatable for folks who have not used tobacco before, and they can make very high levels of nicotine accessible, including to the brain, which is developing in a teenager. The flavors that are used are very appealing to youth, and part of the strategy, there are the ads, then the flavor, and then the nicotine, which is the addictive piece.

The aerosol that is produced from these e-cigarettes can include heavy metals like lead, volatile organic compounds that can be really nasty. Cutting agents can be used that are essentially toxins. And there are also, we were talking about it briefly, ultrafine particles that when they deposit in the lungs may—and you have high exposure over time, they may eventually give us something like a chronic lung condition like silicosis or asbestosis.

So those are the kinds of lung problems that we are facing, and you are really not expecting a 13- or 15- or 17-year-old to be doing things that are going to turn their lungs into that of an 80-year-old.

Mr. POCAN. Yes, I think they even mentioned eyes, too, something with arsenic, if I am right? Or there is some other aspect.

Dr. SCHUCHAT. We don't even know.

Mr. POCAN. Okay.

Dr. SCHUCHAT. CDC has a smoking lab that is now studying aerosols from some of these. And I think they haven't really gone

through the reviews that you would need to do, and the animal studies are concerning.

So I think that is where, unfortunately, we have a generation that is being experimented on right now.

Mr. POCAN. Thank you.

Ms. DELAURO. Thank you. We are going to now move to our second panel. But I think for all of us, I just wanted to say, Doctor—

Mrs. WATSON COLEMAN. Madam Chairwoman? I am sorry—

Ms. DELAURO. Oh, I thought you had—

Mrs. WATSON COLEMAN. I didn't.

Ms. DELAURO. Go for it.

Mrs. WATSON COLEMAN. Thank you, Madam Chair, and thank you very much.

I am so sorry I haven't been here. But I asked my staffer a question, and it was do we know what the FDA is doing? Do you know what the FDA is doing to look at the danger or the perceived danger of these e-cigarettes with marijuana laced, without marijuana laced, with sweetenings and without sweetenings?

Dr. SCHUCHAT. Well, I can comment on two things that the FDA is doing. One thing is the aggressive collaboration as part of this outbreak of lung injury where they and their investigators in States are collecting products for testing, testing a variety of things—the product, the device, the components, which may or may not have been expected, sort of looking for those cutting agents and so forth.

And that they have announced, as part of the administration's announcement in September, that they intend to be issuing guidance related to enforcement of the non-tobacco flavored premarket approval process. So those are the two areas. And CDC is collaborating on the testing of the aerosol.

Mrs. WATSON COLEMAN. That was the other thing I was wondering if they were going to be benefiting from the kind of research that you all are doing and findings that you are doing?

Dr. SCHUCHAT. Yes. We are working very closely with them, as well as with the National Cancer Institute. We have a tri-agency group that is focused on sharing our results as well as coordinating the research and the campaigns and so forth.

Mrs. WATSON COLEMAN. And did I understand you say that they will come out with some recommendations and findings with regard to the non-?

Dr. SCHUCHAT. The non-tobacco flavors. That is what they announced, that flavors—

Mrs. WATSON COLEMAN. The non-flavored?

Dr. SCHUCHAT. Flavors other than tobacco. So they actually have a tobacco-flavored e-cigarette, and they are not intending to issue guidance related to that. But for all of the other flavors, that is what they announced they were going to be developing guidance for because they hadn't yet enforced that guidance or enforced that regulatory authority that they already have.

Mrs. WATSON COLEMAN. But is it—but is it tobacco?

Dr. SCHUCHAT. Yes, it is for the nicotine—

Mrs. WATSON COLEMAN. Is that not a danger? Is that not a possible danger as well?

Dr. SCHUCHAT. Yes, it is. Well, I think the idea is they are all potentially dangerous, but the non-tobacco flavors are particularly attractive to young people. You know, candy, popcorn, bubblegum.

Mrs. WATSON COLEMAN. Yes, as we move forward and have the cigarette industry be more aggressive in its cautionaries, either on the pack or any advertisements or whatever, it just seems to me that this is a new—this is an alternative that we—that has been presented, and we need to be as aggressive in making sure that people don't get addicted or exposed as much as possible.

Thank you. Thank you. I yield back.

Ms. DELAURO. Thank you very, very much, and we would like to—I want to just say thank you so much. The clarity, the lucidity of your explanation, the scientific—you know, making it as easy as possible for us to understand.

And obviously, our continued conversations about recommendations, we will say that like the—I know you are in the business of making recommendations. I think we all want to see the recommendations as strong as possible that they translate into real action by the FDA, which is the regulatory agency.

I am just going to ask the second panel to come up and say thank you to you so very, very much, Dr. Schuchat.

I would like to say to my colleague while we are changing that the FDA currently has the authority. They did not take on this authority to deal with the premarket review either in the last administration or this administration. We would have then been able to know the scientific difficulties or the positive side of these products, and therefore—and also the FDA, to my colleague who asked about advertising, they regulate the advertising as well.

They are a regulatory agency, and quite frankly, in my view, they have abdicated that responsibility.

Thank you, Doctor.

[Pause.]

Ms. DELAURO. Good morning, and thank you very, very much for being here this morning. We will proceed to opening statements from our panelists, including Renee Coleman-Mitchell, who is the commissioner of the Connecticut Department of Public Health. As I mentioned earlier, it was great to have you join me at Yale New Haven Hospital in September to talk about the public health crisis, and it is wonderful to have you with us today.

If I also might add, we want to welcome not only you, but we want to welcome your family who is here today—your son, your daughter, your husband. Really, welcome. I know how proud you are of this lady. She is terrific.

We have also with us Dr. Sally Satel, resident scholar at the American Enterprise Institute; Dr. Bonnie Halpern-Felsher, professor of pediatrics at Stanford University, executive director of the Stanford Tobacco Prevention Toolkit; and Meredith Berkman, co-founder of Parents Against Vaping E-cigarettes.

Public health crisis. Again, thank you for being here. We look forward to the discussion.

Commissioner, your full written testimony will be entered into the hearing record. You are recognized for 5 minutes. Go for it.

Ms. COLEMAN-MITCHELL. Good morning, Chair DeLauro, Ranking Member Cole, and members of the subcommittee.

Thank you for allowing me the opportunity to come before you today with great concern for all our victims who have been misled and misinformed about the human health risks of vaping. As a State health official, I am deeply alarmed by the outbreak of severe lung illnesses and deaths associated with vaping. This is a public health emergency with serious consequences.

I know you join me in expressing our heartfelt sympathy to the families who have lost loved ones. In Connecticut, so far we have 31 cases and 1 death, but any death is too many.

As Dr. Schuchat indicated today, we still do not know what is causing the lung disease outbreak among e-cigarette users, but public health is working tirelessly in partnership with our Federal, State, and local partners to investigate this illness fully so that we can work better to protect the lives of Americans.

What we do know, however, is vaping and e-cigarette products are highly addictive and are unsafe. The younger the age of initiation, the harder it is to stop using these products. Connecticut managed to reduce the high school youth combustible cigarette use rate to less than 4 percent by 2017 by implementing such best practices, which included enacting a clean indoor air law, levying a high excise tax rate, and providing youth education on smoking.

However, the increase in vaping that has overtaken our trend. The Connecticut Youth Tobacco Survey shows that our overall rate of e-cigarette use among all high school students was 14.7 percent in 2017. For high school seniors, the rate is 24.4 percent, nearly 1 in 4.

This is one of the most frustrating facts when it comes to vaping. After decades of work, we substantially decreased youth tobacco use. We were headed in the right direction. But with aggressive marketing campaigns touting interesting flavors and pitching e-cigarettes as safe alternatives to smoking, youth nicotine use is once again on the rise.

I want you to take a quick look at a graph that we have. Are we able to pull it up? And if we are not, I am just going to have to summarize it. All right.

The bottom line is that you have seen over time is comparing Connecticut youth cigarette use versus e-cigarette use among youth. And it was cigarette use gradually went from 25.6 percent in 2000 to 3.5 percent in 2017 versus e-cigarettes at 2.4 percent in 2011, and now at 14.7 percent in 2017.

It shows you what we are up against here in the declining number of young people in Connecticut reporting use of combustible tobacco products. And just in the last couple of years while the introduction of e-cigarettes and vaping, nicotine use is up sharply among our young people. Here is the graph.

And again, what I really just want to emphasize is that you saw over time. This was between 2000 and 2018. It is a gradual progression down in terms of overall youth cigarette use, but look at the trajectory regarding e-vaping, the e-cigarettes and vaping. From 2000 to 2017, look at that. That is alarming because it is going straight sky high. Excuse that pun.

With the introduction of e-cigarettes and vaping, nicotine use is up sharply among our young people. This has wiped out all our gains we made in reducing tobacco use among young people. We

were using all available resources to address the use of e-cigarettes, vaping products, and the lung disease outbreak.

Specifically, on September of this year, I authorized the amendment to the list of reportable diseases by adding unexplained vaping-related injuries. As of October 1st of this year, Connecticut passed T21 legislation, which raised the minimum age from 18 to 21 years of age to purchase all tobacco, e-cigs, and vaping products.

We continue to amend our Indoor Clean Air Act, which we now can proudly say it is 24/7 in regards to prohibiting smoking in indoors workplaces, but also our school grounds and all of our daycare facilities. We have put a tax on vaping products. We are encouraging our residents to use our quit line. We are also getting the word out on media.

We are using, as a State health department, personnel from our infectious disease section, our tobacco prevention section, from our injury section, our toxicologists, and our State lab. We are using their expertise to interview the cases looking at the data involving our tobacco prevention program to enhance our messaging and education programming. These resources are being used for three things—investigating the cases, the completion of the case reports, and for the transmission of that data to CDC.

The greatest danger we face is that vaping-related lung illnesses are not only an outbreak but may, in fact, become an endemic or costly chronic disease. I am going to have to summarize due to the time.

It comes down to this. The question I ask, do you want to wait another 50 years to combat the vaping epidemic? We need to act now. Otherwise, we run the risk of losing a whole generation to severe costly illness or, even worse, what we already have experienced, death.

Ms. DELAURO. Thank you. Dr. Satel.

Dr. SATEL. Thank you, Chairwoman DeLauro, Ranking Member Cole, and the subcommittee, for inviting me.

I am an addiction psychiatrist, a resident scholar at the American Enterprise Institute, and a lecturer at Yale University School of Medicine, where I did my residency and was an assistant professor.

I want to talk about nicotine vaping by smokers as a public health asset, but I will start by briefly addressing the recent outbreak of pulmonary illness and mortality. Crucially, the vast majority of patients, as Dr. Schuchat was telling us, with respiratory failure appear to have used underground, adulterated cannabis vape cartridges. Vitamin E acetate oil, pesticides, and so on, these things cause extreme inflammatory responses that can actually be life-threatening, and that is why the FDA has been warning people to “stop using THC vaping products.”

But the FDA has issued no such warning on users of commercial nicotine vaping products. I will refer to them as e-cigarettes from now on. So while the current rash of lung illnesses and fatalities is a very serious problem, it is not a problem that will be solved through bans involving commercial. Now it could be that counterfeit e-cigarettes are causing some problems, but they won't be solved by bans involving commercial e-cigarette products because those haven't been implemented as a cause.

But moving on to smokers, to be unmistakably clear, the only permissible consumers of e-cigarettes are smokers, period. But kids don't know that, and one in four, as we have heard, have reported vaping at least once within the last month. And a minority actually vape considerably more than that.

If candy and fruit flavors no longer existed, the policy rationale goes, kids would be deterred, and I suspect that is true of a lot of them. The problem is, though, that those bans will harm adult smokers, and they need flavors.

Those flavors are the reason they were able to switch from cigarettes to a much less risky activity, and their preferred flavors are fruit. And if they can't get those fruit-flavored products, many will have two really bad options.

They can go to Walmart, where cigarettes will now be—e-cigarettes will now be banned, but the shelves will be stocked with cigarettes so that they may now resume smoking a much more deadly alternative. Or they can head to the new black market in flavored vapes, and we have already seen what black markets can do.

In the end, it is difficult, if not impossible, to make vaping less appealing to kids by banning flavors without simultaneously making it more difficult for smokers to quit cigarettes with this safer alternative. And I feel I need to repeat "safer" because in all this anxiety, much of it warranted, about teen vaping and certainly about the deaths, I think we have lost this powerful truth, that e-cigarettes, again, do not combust tobacco. That means no smoke, no carcinogenic tar produced.

Are they safe? Nope. No one says they are safe. But they are safer. They do emit toxins. E-cigarette aerosol does have some toxins and some trace metals, but they emit far fewer in number than found in cigarette smoke, and those that are present exist at a much lower level.

The National Health Service in England, which actually has relied considerably on data, and I am happy to provide that, is so confident of the relative safety, it estimates that 95—others have estimated perhaps even 90, even 80 percent, but they have estimated at 95. And hospitals within the National Health Service have vape shops within them. This is their anti-smoking month called Stoptober, and they have promoted vaping.

In the U.S., vaping is the most popular and successful product for quitting smoking. I have data on that, references to that in my testimony, written testimony.

Do scientists need to follow vapers for many years out, decades? Definitely. We need to know the possible long-term effects of inhaling e-cigarette aerosol.

In closing, though, we cannot allow the vaping issue to become a contest between the health of teens and the health of smokers. We can and must protect teens, and we can and must protect smokers. Not through flavor bans, which will lead many to return to smoking, which is probably the deadliest consumer product there is. It will also lead to a market for dangerous counterfeits.

We must pursue a very aggressive series of barriers, Tobacco 21 being the first. There are others in my testimony, written testimony.

I will close by saying e-cigarettes are not a threat. They are an invaluable option for improving smokers' health, adult smokers' health, the ones who have already switched and the 36 million who are still smoking.

Thank you.

[The information follows:]



**Statement before the House Labor, Health, Education
Appropriations Subcommittee On
E-cigarettes: An Emerging Threat to Public Health**

Putting Teen Vaping in Perspective:
Balancing protection of youth with health of smokers

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October 16, 2019

The American Enterprise Institute (AEI) is a nonpartisan, nonprofit, 501(c)(3) educational organization and does not take institutional positions on any issues. The views expressed in this testimony are those of the author.

I am grateful to Chairwoman Rosa DeLauro, Ranking Member Tom Cole, and members of the subcommittee for inviting me to offer my view on this vital public health issue.

I am resident scholar at the American Enterprise Institute and a lecturer at Yale University School of Medicine. My medical expertise is in addiction psychiatry. I also serve on the current National Advisory Board of the Substance Abuse and Mental Health Services Administration. I have worked part time in mental health and methadone clinics in the District. I spent last year in Rust Belt Appalachia (southeastern Ohio) studying the opioid crisis.

Today, I would like to comment on electronic cigarettes and commercial nicotine vaping in the context of two recent developments. The first is the rash of about 1,300 cases of lung injuries and 26 deaths (as of October 11) linked to vaping. The second development is the imposition of non-tobacco flavor bans on e-cigarettes and vaping products. The facts show that the bans would do nothing address the lung injuries and deaths.

I want to emphasize the crucial importance of distinguishing between the cannabis-related products responsible for causing pulmonary illnesses and deaths from nicotine-containing commercial vaping products, which have not caused been identified as the source.

I also highlight the serious unintended consequences imposed upon adult vapers by flavor bans that are aimed at discouraging teen use.

Without question, we must reduce teen vaping but other, non-prohibitionist solutions can help achieve that imperative. We must not impede vital access to vaping products for the 11-14 million adult vapers who might otherwise smoke instead or for the 38 million smokers who could switch to vaping if they cannot quit smoking by other means.

Vaping-Induced Lung Injury

For weeks, the Food and Drug Administration (FDA) has been communicating to the public the dangers of vaping street-bought THC. Most recently, on October 4, the agency released a statement with a headline warning people to “stop using THC vaping products.”¹ According to the FDA, “The best way to avoid potentially harmful effects is to not use THC, including through e-cigarette, or vaping, products...[T]he latest findings from the investigation into lung injuries associated with e-cigarette use, or vaping, suggest products containing THC play a role in the outbreak.”

The lung injury problem is a story of the dangers of the black market, not of vaping. Earlier this month, a California cannabis lab tested counterfeit vapes and found high levels of dangerous chemicals, including vitamin E acetate (a cutting agent used to stretch the amount of THC in vape cartridges), pesticides, and hydrogen cyanide.²

Consumers have been using commercially available vaping devices and nicotine products for

10 years without a single recorded death or any surge of illnesses...until this summer. What we are observing today is consistent with a relatively acute contamination.

Thus, warning smokers in a blanket manner not to vape is a hazard to smokers who have already switched to e-cigarettes and now risk return to smoking combustible cigarettes. After all, vaping is a generic term for an activity that uses a device to inhale substances in aerosolized (droplet) form. FDA's emphasis on THC cartridges targets the actual problem.

The key lesson here is that the tragic cases of lung injury and death are completely separate from the commercially sold vaping products intended to help smokers relinquish cigarettes. Risk communication and policies targeted at THC, not global warnings against vaping, are needed.

Flavor Bans

Background:

On September 11, the Trump administration announced its intention to ban all nontobacco flavored e-cigarette vapes from the market. The impetus for the news was the release of preliminary data from the National Youth Tobacco Survey showing that more than one in four high school students³ had used an e-cigarette ("vaped") within the past month in 2019, with most using flavored products. A week later, the Monitoring the Future Survey revealed that 11.7 percent of high school seniors⁴ reported vaping on 20-30 days out of the past month in 2019. Both results represented increases over the year before. (Notably, however, earlier data show that current and former smoking students are far more likely to fall into the frequent-use category than are never-smoking teens.)

These worrisome data spurred the administration to curb the sale of vaping liquid with fruit and candy flavors in order to dissuade teens from use. The ambient alarm surrounding lung illness and deaths – particularly in light of erroneous impression that e-cigarettes played a role --surely contributed to the impetus behind decisions to ban.

As of October 9, Massachusetts, Michigan, Montana, New York, Oregon, Rhode Island, and Washington have moved to ban most flavored nicotine vaping products. The California Department of Public Health recently warned against all vaping devices, and the governor of Massachusetts issued a four-month ban on all vaping products. Los Angeles County voted last week to ban flavored tobacco products, and dozens of other California cities² have enacted or are considering similar legislation.

The problem with bans:

1. As I have explained, a ban on flavors is completely irrelevant to the outbreak of lung disease. Eliminating flavored nicotine e-liquids will not prevent further cases of lung disease because those products had nothing to do with the outbreak.

2. Under a non-tobacco flavor ban, a sizeable number of vapers will resume smoking – after all, cigarettes will remain untouched on convenience store shelves and that is where many will head. Others will seek out counterfeit enterprises. Others will seek out counterfeit enterprises, as Mitchell Zeller, head of the FDA’s Center for Tobacco Products, confirmed in a declaration to a Maryland court this June.⁶ “Dramatically and precipitously reducing availability of these products could present a serious risk that adults, especially former smokers, who currently use ENDS products and are addicted to nicotine would migrate to combustible tobacco products,” he wrote.

Generally, bans push users to patronize underground marketplaces, which are breeding grounds for the worst manufacturing practices and products including tainted nicotine liquids, defective batteries, and heating coils.

Adult Smokers – The intended consumer:

The central fact is that vaping is much less hazardous than smoking. This is a relative statement - vaping *reduces* harm, but does not obliterate it completely. Classic harm reduction efforts include giving clean needles to heroin users and disseminating condoms and pre-exposure prophylaxis (PrEP),⁷ and imparting information on safe sex practices for populations at risk for HIV/AIDS. Such practices are widely endorsed by the public health establishment

But it is difficult to endorse nicotine harm reduction with the enthusiasm it warrants if one doubts that vaping is actually reducing harm.⁸ Indeed, a thick haze of misinformation about e-cigarettes that has obscured their value. These have included unwarranted claims of e-cig-induced heart attacks⁹ and “popcorn lung” (obstruction of the smallest pulmonary airways), and nicotine as a cause of cancer.¹⁰

Accordingly, public opinion regarding their relative safety and value as quit devices has turned negative over the years.

Fortunately, evidence points to significantly less hazard, due to the fact that e-cigarettes do not burn tobacco as do conventional cigarettes. The latter release 7,000 chemical compounds including 70 known human carcinogens. In contrast, electronic cigarettes heat a solution of nicotine, propylene glycol, glycerin, flavorings, and water. Although they release some toxins, the overall toxicological profile is far less hazardous than that of cigarette smoke.

One representative analysis from 2018, using data from the Food and Drug Administration and published in the *Journal of the American Medical Association* shows that e-cigarettes emit only a fraction of the exposure of known tobacco-related toxicants that result from smoking.¹¹ Some toxicants are present in much lower levels in e-cigarette aerosol while others are completely undetectable.¹²

To be sure, epidemiologists need to continue monitoring vapers for the development of

possible long-term health effects of regularly inhaling propylene glycol, glycerin, and flavors. This uncertainty is a compelling reason for non-smokers to reject vaping. But it should not stop smokers who have failed to quit smoking or don't want to, especially if they haven't been helped by FDA approved forms of nicotine replacement such as gum or the patch.

Vaping is now the most popular¹³ and successful¹⁴ product for quitting smoking relative to nicotine patches or gum. And in response to the prediction that the 11- 14 million vapers have "re-normalized" smoking in America, reassurance is at hand: the U.S. adult smoking is at 14 percent,¹⁵ the lowest level ever recorded.

Flavors, especially fruity ones, are a key element of the appeal of vaping to adult smokers. Such fruit and candy flavors, which were initially created in do-it-yourself fashion by independent vapers,¹⁶ are in great demand by adults and thus now dominate the market.¹⁷ In 2018, the largest flavor preference survey of adult vapers in the United States found fruit and dessert flavors to be the most popular by far; only a minority of the nearly 70,000 participants used tobacco flavors, and their use has decreased over time.¹⁸ In large-scale consumer surveys¹⁹, adults who vape overwhelmingly report that non-tobacco flavors and flavor variability²⁰ matter to them and help keep them away from smoking.

In sum, vaping products are intended to help smokers relinquish cigarettes. They help adult smokers to quit smoking and are substantially less dangerous than smoking.

As with any public health intervention, the unintended consequences of regulatory policies aimed at teen vaping must be kept in the forefront of our thinking. To appreciate why curbing adult access has such significant public health implications, we need to acknowledge the vast health benefits of vaping for smokers.

Teens:

Fortunately, the predictions that vaping would serve as a "gateway" into smoking for has not materialized. Teens now smoke cigarettes at the lowest rates in history and have experienced unprecedented decreases in smoking prevalence precisely during the period of vaping's popularity. Further, data from National Youth Tobacco Survey reveal that frequent vaping (e.g. use on 20 or more days of the past 30) is not common in teens who had not already used tobacco. Specifically, vaping occurred in 0.1 percent of never tobacco users in 2017 and 1.0 percent in 2018.²¹ Data from 2019 are pending and might show an increase.

If a gateway were present, we should see more smoking among teens. Yet, smoking among high school students has dipped to a new low this year, with 5.8 percent report having smoked at least once in the preceding month-- a pattern suggesting that vaping serves more as an off-ramp from smoking than as an entryway for teens.²² By comparison, in 2014, the first year of vaping's use by significant numbers of students,

smoking prevalence was twice as high. Just two decades ago, well over a third of high school seniors had smoked in the past 30 days. The biggest risk of all for kids – cigarette smoking – is becoming vanishingly small.

Claims that nicotine damages the teen brain rest on shaky empirical grounds. For one, many of the studies were conducted in rodents, making them difficult to translate into humans. Second, those done in teens examined smoking not pure nicotine. Any effects found could be attributed to products of combustion, not nicotine per se. Third, and most compelling to me, is the fact that decades ago a much higher percentage of teens smoked and they more likely to smoke many more days per month than teens today. However, if nicotine exposure caused brain damage, we surely would have observed it in that much larger and much more intensely nicotine-exposed cohort.

To be sure, the absence of a documented gateway effect and the exaggerated claim regarding nicotine-induced brain damage do not diminish the importance of reducing teen vaping, but they should reduce alarm among parents and policy-makers.

Pragmatic Considerations

It is difficult, if not impossible, to make vaping less appealing to kids by banning non-tobacco flavors without simultaneously making it less compelling to adults.

Therefore, in my view, the heavy and relentless focus should be on strengthening barriers to teen access to nicotine vaping products. The FDA has an extensive program for preventing and combatting use. Here are several other options, many of which have received a lot of attention already, including a law raising the age of tobacco purchase and consumption to age 21. Congress should exercise its power to raise the age of tobacco purchase and consumption to 21.

Other interventions include banning TV ads and print advertising except in adult-only publications or media (in which adults are >85 percent of audience). No longer should juvenile terms such as “candy,” “bubble gum,” “cotton candy,” “cake” or variants, packaging that resembles juice boxes, soft drinks, soda, cereal, candy, or desserts, or packaging that uses cartoons or cartoon characters be allowed.

Enforcement should also close loopholes by banning sales on third-party marketplaces, such as Alibaba, Amazon, and eBay where third party sales from unregulated, unlicensed tobacco product distributors are not age verified. In addition, a “Three Strikes and You’re Out” rule should be adopted, providing that any retailer accumulating three violations in three years for selling nicotine vapor products to minors loses the right to sell nicotine vapor products. Also, more rigorous age verification practices involving software or technology should be instituted for all online sales and all brick and mortar sales. These are only some of the more aggressive approaches that can be deployed.

Conclusion

The purview of public health is the nation's entire population of vulnerable people, not exclusively its youth. That includes adult smokers, particularly those who smoke at disproportionately high rates, namely, people suffering mental illness, working class men and women, those who live in rural areas, Native Americans, lesbian, gay and bisexual adults, and military veterans.²³

We must not allow the intense focus on teen use – warranted though it is – to divert almost all attention from the benefits of vaping for adult smokers who are dying at the rate of 480,000 per year from a terrible habit.

Benefits to smokers unappreciated: Intrinsic to the controversy we confront today is the fact that the benefits of vaping to smokers are not widely appreciated. Optimal analysis of the risks and benefits of vaping to population as a whole – a public health imperative – simply cannot proceed unless the significant advantages of vaping to smokers are taken into account.

And when the known realities are considered, it becomes clear that we are on an irrational path: we condone smoking, an indisputably dangerous activity, as we impose bans on non-tobacco flavors which will the therapeutic power of much lower risk alternative for smokers.

Harmful unintended consequences of bans: A non-tobacco flavor ban, let alone an outright ban on all vaping, will almost surely harm adults who have already switched or those who could do so in the future, as well as teens who claim they are addicted to nicotine.

Reject a false choice: Regrettably, the vaping issue has been cast as a contest between the health of teens and the health of smokers. But we should not succumb to this false choice. We can protect teens through more aggressive barriers to access. At the same time, we can save smokers' lives and combat the leading cause of preventable death in the world by preserving adult smokers' access to a valuable smoking-cessation method.

¹ https://www.fda.gov/news-events/press-announcements/statement-consumer-warning-stop-using-thc-vaping-products-amid-ongoing-investigation-lung-illnesses?utm_source=Eloqua&utm_medium=email&utm_term=stratcomms&utm_content=pressrelease&utm_campaign=CTP%20News%3A%20Vaping%20Update%20-%2010419

² <https://www.businessinsider.com/study-counterfeit-vapes-contain-vitamin-e-pesticides-and-hydrogen-cyanide-2019-10>

³ <https://www.usatoday.com/story/news/politics/2019/09/11/donald-trump-wants-to-ban-flavored-vapes-discourage-young-people-from-e-cigarettes/2284270001/>

⁴ Miech R, Johnston L, O'Malley P. et al., Trends in adolescent vaping, 2017-2019. *New England Journal of Medicine*. 2019 September 18 at <https://www.nejm.org/doi/full/10.1056/NEJMc1910739>

⁵ <https://californiahealthline.org/news/states-target-vaping-with-bans-in-california-the-action-is-local/>

⁶ Zeller M. (Head of Center for Tobacco Products, FDA) "[...] mass market exit of such products would limit the availability of a potentially less harmful alternative for adult smokers seeking to transition or stay away from combustible tobacco products. Dramatically and precipitously reducing availability of these products could present a serious risk that adults, especially former smokers, who currently use ENDS products and are addicted to nicotine would migrate to combustible tobacco products, even if particular ENDS products ultimately receive marketing authorization and return to the market later. Declaration to the US District Court for the District of Maryland Case 8:18-cv-00883-PWG Doc 120-1, para 15. June 12, 2019.

⁷ A combination of two HIV medicines (tenofovir and emtricitabine)

⁸ Compare the US with the U.K.'s National Health Service which explicitly encourages smokers to use e-cigarettes.

⁹ <https://www.usatoday.com/story/news/health/2019/07/17/vaping-heart-attacks-false-claims-sexual-harassment-allegations/1676473001/>

¹⁰ Refuting proposition <https://blog.dana-farber.org/insight/2018/07/nicotine-cause-cancer/>

¹¹ Goniewicz ML, Smith DM, Edwards KC, et al., Comparison of Nicotine and Toxicant Exposure in Users of Electronic Cigarettes and Combustible Cigarettes. *JAMA Open Network*, Dec. 14, 2008 at

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2718096>

¹² See also <https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review> and excellent lecture by Lynne Dawkins PhD <https://www.clivebates.com/lynne-dawkins-e-cigarettes-an-evidence-update/>

¹³ https://www.cdc.gov/pcd/issues/2017/16_0600.htm

¹⁴ Hajek P, et al.,. A randomized trial of e-cigarettes versus nicotine-replacement therapy. *New England Journal of Medicine*. 2019 Feb 14;380(7):629-637 at <https://www.ncbi.nlm.nih.gov/pubmed/30699054>

¹⁵ <https://www.cdc.gov/media/releases/2018/p1108-cigarette-smoking-adults.html>

¹⁶ <https://www.inquirer.com/opinion/commentary/vaping-flavor-e-cigarettes-teen-smoking-20190921.html>

¹⁷ Russell C, McKeganey N, Dickson T, Nides M. Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduct J. BioMed Central*; 2018 Jun 28;15(1):33.

¹⁸ Russell C, McKeganey N, Dickson T, Nides M. Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduct J. BioMed Central*; 2018 Jun 28;15(1):33. <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0238-6>

¹⁹ <https://www.forbes.com/sites/jacobusillum/2014/07/17/survey-shows-adults-who-use-e-cigarettes-to-quit-smoking-prefer-allegedly-juvenile-flavors/#7c33c85f8fc1>

²⁰ Farsalinos K, Romagna G, Tsiapras D, et al., Impact of flavor variability on electronic cigarette use experience: an internet survey. *International Journal of Environmental Research and Public Health*. 2013 December 17; 10(12), 7272-7282. <https://www.mdpi.com/1660-4601/10/12/7272>

²¹ Jarvis MJ, West R, Brown J. Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey reveal about high school e-cigarette use in the USA? (Preprint). Qeios. 2019 Oct 2 at <https://www.qeios.com/read/article/384> (awaiting review)

²² Levy DT, Warner KE, Cummings KM, et al., Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check. *Tob Control*, Nov. 2018 at <https://tobaccocontrol.bmj.com/content/early/2018/10/31/tobaccocontrol-2018-054446>). See also <https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non> (this shows last 30 days smoking); shows off ramp exceeds on ramp: <https://vaping.org/progressive-policy-institute-vaping-most-effective-tool-for-quitting/>; <https://rodutobaccotruth.blogspot.com/2019/02/teen-smoking-to-vaping-is-more-frequent.html>

²³ <https://www.lung.org/our-initiatives/tobacco/reports-resources/sotc/by-the-numbers/top-10-populations.html>

Ms. DELAURO. Thank you. Dr. Halpern-Felsher.

Ms. HALPERN-FELSHER. Thank you, Chair DeLauro, Ranking Member Cole, and other members of the subcommittee, for giving me the opportunity to speak with you on this important and urgent topic on youth e-cigarette use.

I am a developmental psychologist with additional training in adolescent and young adult health, and my research, prevention, and policy work for the past 25 years has focused on factors involved in youth tobacco use.

As you know, we have seen an unprecedented number of youth using and addicted to e-cigarettes, with this largely due to Juul, which accounts for 70 to 80 percent of the e-cigarette market share. But I would actually argue that these statistics are underestimates. I go around the country speaking to students, parents, and educators, all of whom tell me that 50 to 75 percent of the students in their schools are using e-cigarettes.

Whether the numbers truly are 27 percent or 75 percent or somewhere in between, we clearly have a vaping youth epidemic, and I would call it a Juul epidemic. Importantly, there is absolutely no difference in e-cigarette use among adolescents based on sex, race/ethnicity, socioeconomic status, or geographic region. Let me emphasize this. Regardless of income, it is easy for youth to obtain e-cigarettes legally and illegally through friends, on the Internet, and through other means.

So why am I concerned about e-cigarettes? Well, first, let us discuss nicotine. As you heard earlier, unlike cigarettes and many e-cigarettes products, they use ammonia and sugars to enhance the delivery and absorption of nicotine to the body. But Juul has patented a salt-based nicotine, whereby benzoic acid is added to change the pH level of the product to help deliver more nicotine to the brain faster with less throat hit, making it more appealing and more addictive to youth.

Moreover, while earlier versions of e-cigarettes had between 0 and 36 milligrams of nicotine per milliliter, Juul and other newer pod-based products have at least 59 milligrams per milliliter of nicotine.

Now you may hear that that translates to about one pack of cigarettes, but actually, in our lab, we have looked at it and done some research and the math to show that it is actually more like the nicotine found in one and a half to two packs of cigarettes. It is, therefore, no wonder, given the amount and the type of nicotine that we have, that we are seeing more and more youth using and addicted to these products.

Second, aside from or really in addition to the current concern over the vaping-related lung illnesses and deaths that we have heard about today that may or may not be caused by nicotine e-cigarettes, there is clear evidence that the flavorants and other chemicals that are in nicotine e-cigarettes cause lung, heart, and other health problems.

Third, schools are heavily impacted. Schools are spending an enormous amount of time, money, and resources directly related to the e-cigarette epidemic. Schools are not equipped to handle the number of students caught using e-cigarettes, nor can they provide addiction treatment services due to legal and/or staffing con-

straints. And yet schools are frantically trying to find ways to help prevent and reduce use of e-cigarettes in their schools and their communities.

The demand for our toolkit, for example, increased dramatically in the past 2 years. In 2018, we trained about 730 educators to use our prevention toolkit. In just the first 9 months of 2019, we have already trained over 1,500 educators, and we have reached well over a million students in the past 2 years.

Fourth, there is a significant impact of e-cigarette use on non-using students. Youth are frustrated by the constant disruptions of students using e-cigarettes, the disciplinary actions needed, and concerns over peers who use e-cigarettes having diminished athletic and academic abilities.

Finally, as was said earlier, we have absolutely no data to inform e-cigarette cessation for youth. There are no nicotine replacement therapies or other medicines approved by the FDA for anybody under 18.

So action is really needed now, including eliminating flavored tobacco products, including mint and menthol; raising taxes to ensure that e-cigarette devices and e-liquids have the same price point as other tobacco products; enacting a nicotine standard that applies to e-cigarettes and all tobacco products; prohibiting the marketing of e-cigarettes as well as product placement, celebrity sponsorships, and so on; prohibiting coupons, other promotional materials; and regulating the products. The FDA has the authority to do these now, including pulling these products off the market.

So, finally, in conclusion, there is an urgent need for education, prevention, and cessation programs in schools, for parents, and for healthcare providers. It is important to note that such strategies should not be conducted by the tobacco or e-cigarette companies as there has been a history of these companies providing ineffective and often inappropriate, misleading, and harmful messages to youth.

I look forward to discussing this more. Thank you.

[The information follows:]

**Public Health Emergency Needing Action Now:
Epidemic Youth Use of E-cigarettes**

Written Testimony of Bonnie Halpern-Felsher, PhD, FSAHM

Professor of Pediatrics, Division of Adolescent Medicine, Stanford University

Founder and Executive Director, Tobacco Prevention Toolkit

Submitted to the U.S. House of Representatives, Labor-HHS-Education Appropriations
Subcommittee, Congressional Hearing, *E-Cigarettes: An Emerging Public Health Threat*

Congresswoman Rosa DeLauro, Chair

October 16, 2019

I thank you for the opportunity to provide written and oral testimony on this important and urgent topic, youth e-cigarette use. As a developmental psychologist with additional training in adolescent and young adult health, my research, prevention, and policy work over the past 25 years has focused on factors promoting and preventing adolescent and young adult tobacco use. In my testimony, I will provide data on youth use of tobacco including e-cigarettes, health and social effects of e-cigarettes, risk factors for use, significant gaps in our knowledge, and needed policy, prevention, and cessation efforts.

Tobacco Usage Rates

We have seen a decline in youth use of conventional, combustible cigarettes over the past few years, with national data showing that far fewer than 10% of youth in the

US report use of cigarettes.¹ However, since 2014, we have seen an alarming increase in youth tobacco use, owing to e-cigarette use. The most recent data from the National Youth Tobacco Survey show that 27.5% of youth have reported using an e-cigarette in the past 30 days.² This translates to more than 1 in 5 high school students using e-cigarettes. Those who do use e-cigarettes do so more frequently than other tobacco products, in part because youth are able to use e-cigarettes all day and night.

However, I would argue that these statistics are vastly underestimated. I go around the country speaking to students, parents, and educators, all of whom tell me that **50%-75% of the students are using e-cigarettes**. In my 25 years of studying adolescent tobacco use, I have never seen such a quick surge in tobacco product use and related addiction outcomes as I have seen in the past 3 years. This surge, as explained below, is largely due to the increase in popularity of JUUL,³ which controls 70-80% of the e-cigarette market.⁴ We have also seen an uptick in the number of youth reporting cigarette use^{5,6,7} and overall tobacco use,⁸ likely due to numerous studies showing that youth who use e-cigarettes are as much as four times more likely to then go on to use

¹ <https://www.cdc.gov/vitalsigns/youth-tobacco-use/>

² <https://www.fda.gov/tobacco-products/youth-and-tobacco/youth-tobacco-use-results-national-youth-tobacco-survey>

³ McKelvey, K., Baiocchi, M., **Halpern-Felsher, B.** Adolescents' and young adults' use and perceptions of pod-based electronic cigarettes. *JAMA Netw Open*. 2018 Oct 05;1(6):e183535. PMID:30646249.

⁴ LaVito A. Popular e-cigarette Juul's sales have surged almost 800 percent over the past year. <https://www.cnbc.com/2018/07/02/juul-e-cigarette-sales-have-surged-over-the-past-year.html>. Published July 2, 2018. Accessed August 10, 2018.

⁵ Berry KM, Fetterman JL, Benjamin EJ, et al. Association of Electronic Cigarette Use With Subsequent Initiation of Tobacco Cigarettes in US Youths. *JAMA Network Open*. 2019;2(2):e187794-e187794

⁶ Soneji S, Barrington-Trimis JL, Wills TA, et al. Association between initial use of e-cigarettes and subsequent cigarette smoking among adolescents and young adults: a systematic review and meta-analysis. *JAMA pediatrics*. 2017;171(8):788-797

⁷ Chaffee BW, Watkins SL, Glantz SA. Electronic cigarette use and progression from experimentation to established smoking. *Pediatrics*. 2018 Mar 5:e20173594

⁸ <https://www.cdc.gov/vitalsigns/youth-tobacco-use/>

cigarettes,^{9,10,11} placing them at risk for the same smoking-related illnesses and costs we have strived so hard to ameliorate.

Importantly, unlike recent data seen for cigarette, smokeless tobacco use, or cigar use, there is **no sociodemographic characteristic** or cluster of characteristics putting youth at more or less risk for e-cigarette or Juul use. That is, **there is no difference in Juul or e-cigarette use among adolescents based on sex, race/ethnicity, socioeconomic status, or geographic region.**¹²

Why I am concerned about e-cigarettes?

E-cigarettes have **nicotine**. While the original and earlier versions of e-cigarettes didn't have as much nicotine, with ranges between 0-36 milligrams per milliliter, the newer pod-based products, made popular by Juuls, have at least 41 milligrams per milliliter of nicotine. That translates into the amount of nicotine found in up to 1.5 to 2 packs of cigarettes.

It is important to discuss Juul's patented salt-based nicotine. Unlike cigarettes and other e-cigarette products which use ammonia and sugars to enhance the delivery and absorption of nicotine to the body, Juul has a salt-based nicotine. Benzoic acid is added to help deliver high amounts of nicotine rapidly and effectively to the brain. Products with salt-based nicotine can allow for more frequent use, increasing their

⁹ Berry KM, Fetterman JL, Benjamin EJ, et al. Association of Electronic Cigarette Use With Subsequent Initiation of Tobacco Cigarettes in US Youths. *JAMA Network Open*. 2019;2(2):e187794-e187794

¹⁰ Soneji S, Barrington-Trimis JL, Wills TA, et al. Association between initial use of e-cigarettes and subsequent cigarette smoking among adolescents and young adults: a systematic review and meta-analysis. *JAMA pediatrics*. 2017;171(8):788-797

¹¹ Chaffee BW, Watkins SL, Glantz SA. Electronic cigarette use and progression from experimentation to established smoking. *Pediatrics*. 2018 Mar 5:e20173594

¹² Kann L, McManus T, Harris WA, et al. Youth risk behavior surveillance—United States, 2017. *MMWR Surveillance Summaries*. 2018 Jun 15;67(8):1

potential for addiction because it feels less harsh on the throat. As such, Juul is engineered to easily deliver more nicotine to the brain, faster, with less harshness, making it more appealing for youth.

Nicotine is harmful. Aside from being a toxicant, nicotine is highly addictive. It actually causes changes to the brain chemistry.¹³ Given that brain development continues until the age of about 25, youth are significantly more likely to become addicted to nicotine than are adults. Data going back decades has shown that almost 90% of addicted adult cigarette smokers started using when they were younger than 18.¹⁴ Indeed, data as well as my personal experience from visiting with parents and schools throughout the country show that youth are addicted to e-cigarettes, with recent studies showing that youth who use Juuls use them more often and are more likely to show signs of addiction than youth using other tobacco products.¹⁵ Nicotine addiction is also related to depressive disorders and other mental health co-morbidities.^{16,17,18} Other effects of nicotine include poisoning and toxicity, vomiting, nausea, and tachycardia.¹⁹ We also know that there has been a significant increase in the number of calls to poison centers, as babies and children consume the e-liquid as it tastes and smells like candy.

¹³ Kandel ER, Kandel DB. A molecular basis for nicotine as a gateway drug. *New England Journal of Medicine*. 2014;371(10):932-943

¹⁴ <https://www.cdc.gov/vitalsigns/youth-tobacco-use/>

¹⁵ McKelvey, K., Baiocchi, M., Halpern-Felsher, B. Adolescents' and young adults' use and perceptions of pod-based electronic cigarettes. *JAMA Netw Open*. 2018 Oct 05;1(6):e183535. PMID:30646249.

¹⁶ King JL, Reboussin BA, Spangler J, Ross JC, Sutfin EL. Tobacco product use and mental health status among young adults. *Addictive behaviors*. 2018;77:67-72

¹⁷ WHO. ICD-11 for mortality and morbidity statistics. World Health Organization. Published 2018. Accessed April 22, 2019.

¹⁸ APA. *Diagnostic and statistical manual of mental disorders*. . Fifth Edition ed. Arlington: American Psychiatric Publishing; 2013.

¹⁹ Cameron JM, Howell DN, White JR, Andrenyak DM, Layton ME, Roll JM. Variable and potentially fatal amounts of nicotine in e-cigarette nicotine solutions. *Tobacco control*. 2014 Jan 1;23(1):77-78

Use of e-cigarettes has also been associated with impaired blood vessels, increasing the risk of heart attacks²⁰ and progression of cancerous tumors.²¹

However, youth are unaware of the amount of nicotine in a Juul pod, and don't recognize the addictive potential or harm of nicotine found in Juuls or other e-cigarettes.²² This confusion is not surprising given that the Juul packaging simply says that the product contains 5% strength, and some saying 5% nicotine, but to a young person and even many adults, that 5% does not translate to the actual amount of nicotine contained within the Juul pod.

I also worry about the **other chemicals found in e-cigarettes**. E-cigarettes have flavorants such as diacetyl, a buttery flavor found in popcorn, as well as vanillin and cinnamaldehyde. These have been shown to cause respiratory, lung, and other illness and effects,^{23,24,25,26} as well as recent evidence that mint and menthol flavored e-cigs have pulegone, a carcinogen.²⁷ Further, Juuls have benzoic acid, which can irritate the

²⁰ Alzahrani T, Pena I, Temesgen N, Glantz SA. Association between electronic cigarette use and myocardial infarction. *American journal of preventive medicine*. 2018;55(4):455-461

²¹ Sanner T, Grimsrud TK. Nicotine: carcinogenicity and effects on response to cancer treatment—a review. *Frontiers in oncology*. 2015;5(196)

²² McKelvey, K., Baiocchi, M., **Halpern-Felsher, B.** Adolescents' and young adults' use and perceptions of pod-based electronic cigarettes. *JAMA Netw Open*. 2018 Oct 05;1(6):e183535. PMID:30646249.

²³ Lee, W. H., Ong, S.-G., Zhou, Y., Tian, L., Bae, H. R., Baker, N., ... Wu, J. C. (2019). Modeling Cardiovascular Risks of E-Cigarettes With Human-Induced Pluripotent Stem Cell-Derived Endothelial Cells. *Journal of the American College of Cardiology*, 73(21), 2722–2737. <https://doi.org/10.1016/j.jacc.2019.03.476>

²⁴ Fetterman, J. L., Weisbrod, R. M., Feng, B., Bastin, R., Tuttle, S. T., Holbrook, M., ... Hamburg, N. M. (2018). Flavorings in Tobacco Products Induce Endothelial Cell Dysfunction. *Arteriosclerosis, Thrombosis, and Vascular Biology*, 38(7), 1607–1615. <https://doi.org/10.1161/ATVBAHA.118.311156>

²⁵ Glynos, C., Bibli, S.-I., Katsaounou, P., Pavlidou, A., Magkou, C., Karavana, V., ... Papapetropoulos, A. (2018). Comparison of the effects of e-cigarette vapor with cigarette smoke on lung function and inflammation in mice. *American Journal of Physiology-Lung Cellular and Molecular Physiology*, 315(5), L662–L672. <https://doi.org/10.1152/ajplung.00389.2017>

²⁶ Madison, M. C., Landers, C. T., Gu, B.-H., Chang, C.-Y., Tung, H.-Y., You, R., ... Kheradmand, F. (2019). Electronic cigarettes disrupt lung lipid homeostasis and innate immunity independent of nicotine. *The Journal of Clinical Investigation*, 129(10), 4290–4304. <https://doi.org/10.1172/JCI128531>

²⁷ Jabba SV, Jordt SE, Risk Analysis for the Carcinogen Pulegone in Mint- and Menthol-Flavored e-Cigarettes and Smokeless Tobacco Products. *JAMA Intern Med*. 2019 Sep 16. doi: 10.1001/jamainternmed.2019.3649. [Epub ahead of print]

lungs, nose and throat, and cause coughing and shortness of breath. The levels of secondhand exposure vary across e-cigarette devices; however, bystanders may inhale up to 1/10th the levels of nicotine and aerosol as in a conventional cigarette.²⁸ **Taken together, aside from the current concern over the vaping-related lung illnesses and deaths that may or may not be caused by nicotine e-cigarettes, there is clear evidence that e-cigarettes do cause lung as well as heart and other health problems.**

It is also important to note that the e-cigarette companies are often misleading consumers and potential consumers as to what ingredients are in their products. For example, while Juul indicates that their e-liquids contains nicotine, benzoic acid, glycerol, propylene glycol, natural oils, and flavorants, an independent scientific study showed that there were 59 chemicals in Juul e-liquid.²⁹

There is also concern about the **impact of e-cigarette use on non-using students**. I am constantly told by youth and educators that the non-using students are frustrated by the constant disruptions of students using e-cigarettes, the needed disciplinary actions needed, and the stigma now placed on students *not* using.

Why are youth using e-cigarettes?

There are a number of reasons why youth are attracted to using e-cigarettes. I will focus on **flavors, marketing, and cost**. There are over 7,000 **flavors** available for e-cigarettes, including flavors that attract young and new users, such as mint, menthol, fruit, and candy. These flavors appeal to new users by masking the harsh taste of

²⁸ Grana R, Benowitz N, Glantz SA. E-cigarettes: a scientific review. *Circulation*. 2014;129(19):1972-1986

²⁹ <https://pubs.acs.org/doi/10.1021/acs.chemrestox.8b00381>

tobacco, and in the case of e-cigarettes, resulting in a more pleasant smell than that found with tobacco alone.³⁰ The vast majority of youth in the US who use e-cigarettes initiate with flavored products, namely fruit and mint/menthol.³¹ Adolescents are more likely to report interest in trying an e-cigarette from a friend if it is menthol/mint-, candy-, or fruit-flavored than if unflavored. Most youth e-cigarette users reported they would quit if flavors were unavailable.^{18,19,20,21,22,23} Flavored (vs. unflavored) e-cigarette ads elicit greater appeal and interest in buying and trying e-cigarettes; and the appeal of ads marketing flavors is linked to rapid and persistent adoption of e-cigarettes among youth.^{32,33,34,35,36,37}

Cost. Youth are extremely price sensitive. Yet, the tobacco products youth use most, e-cigarettes, are often LESS expensive than other tobacco products including e-cigarettes. If we increase their price, through taxes on par with other tobacco products, we will reduce youth use.

Marketing of e-cigarettes is of major concern. Trendy, technologically-savvy, relaxed, sexualized words and images are used to advertise e-cigarettes, including Juul.

³⁰ Brown JE, Luo W, Isabelle LM, Pankow JF. Candy flavorings in tobacco. *N Engl J Med*. 2014;370(23):2250-2252.

³¹ McKelvey, K., Baiocchi, M., Halpern-Felsher, B. Youth Say Ads for Flavored E-liquids are for Them. *Addictive Behaviors*, in press.

³² Liang Y, Zheng X, Zeng DD, Zhou X. Impact of flavor on electronic cigarette marketing in social media. 2015:278-283.

³³ Vasiljevic M, Petrescu DC, Marteau TM. Impact of advertisements promoting candy-like flavoured e-cigarettes on appeal of tobacco smoking among children: An experimental study. *Tob Control*. 2016;25(e2):e107-e112.

³⁴ Ambrose B, Day H, Rostron B, et al. Flavored tobacco product use among us youth aged 12-17 years, 2013-2014. *J Am Med Assoc*. 2015;314(17):1-3. doi:10.1001/jama.2015.13802.

³⁵ Pepper JK, Ribisl KM, Brewer NT. Adolescents' interest in trying flavoured e-cigarettes. *Tob Control*. 2016;25(Suppl 2):ii62-ii66. doi:10.1136/tobaccocontrol-2016-053174.

³⁶ Morean ME, Butler ER, Bold KW, Kong G, Camenga DR, Cavallo DA, Simon P, O'Malley SS, Krishnan-Sarin S. Preferring more e-cigarette flavors is associated with e-cigarette use frequency among adolescents but not adults. *PLoS one*. 2018 Jan 4;13(1):e0189015

³⁷ Loukas A, Jackson CD, Marti CN, Perry CL. Flavored tobacco product use among youth and young adults: What if flavors didn't exist? *Tob Regul Sci*. 2017;3(2):168-173.

To capitalize on e-cigarette popularity among youth, manufacturers use social media channels to promote their products. Often such social media is driven by adolescents, although nearly 80% of the social media is industry driven in some platforms.³⁸ JUUL's principal advertising themes were closely aligned with Marlboro advertising (pleasure/relaxation, socialization/romance, style/ identity, and satisfaction). JUUL's advertising was widely distributed on social media channels, amplified by hashtag extensions, and catalyzed by compensated influencers. Its social media channels, especially Instagram, have a viral presence although JUUL itself has disbanded use of social media in the United States. JUUL's success has led to the marketing of a number of copy-cat devices.³⁹

Misperceptions. Given the marketing, misleading labelling of e-cigarette packaging, flavors, and other messaging received by youth, it is not surprising that adolescents underestimate the health risks of Juul and other e-cigarettes. Youth don't always recognize that e-cigarettes including Juul contain any tobacco⁴⁰ or nicotine,⁴¹ many youth also believe that e-cigarettes are safer than cigarettes,⁴² and that e-cigarettes just contain water vapor.³¹ Further, adolescents believe that second-hand

³⁸ Clark EM, Jones CA, Williams JR, et al. Vaporous marketing: uncovering pervasive electronic cigarette advertisements on Twitter. *PLoS One*. 2016;11(7):e0157304

³⁹ Jackler RK, Ramamurthi D. Nicotine arms race: JUUL and the high-nicotine product market. *Tob Control*. February 2019;tobaccocontrol-2018-054796. doi:10.1136/tobaccocontrol-2018-054796

⁴⁰ Gorukanti A, Delucchi K, Ling P, Fisher-Travis R, Halpern-Felsher B. Adolescents' attitudes towards e-cigarette ingredients, safety, addictive properties, social norms, and regulation. *Preventive medicine*. 2017;94:65-71

⁴¹ Roditis ML, Halpern-Felsher B. Adolescents' perceptions of risks and benefits of conventional cigarettes, e-cigarettes, and marijuana: a qualitative analysis. *Journal of Adolescent Health*. 2015;57(2):179-185

⁴² Gorukanti A, Delucchi K, Ling P, Fisher-Travis R, Halpern-Felsher B. Adolescents' attitudes towards e-cigarette ingredients, safety, addictive properties, social norms, and regulation. *Preventive medicine*. 2017;94:65-71

smoke from e-cigarettes is not a risk,³² and find it more acceptable to use e-cigarettes indoors and outdoors compared to cigarettes.⁴³

Are e-cigarettes important for adult cigarette cessation?

It is important to emphasize that, while some smokers have successfully quit smoking using e-cigarettes (notably daily users of high nicotine delivery systems), most smokers who use e-cigarettes are *less* not more likely to quit smoking. In fact, the overall effect of e-cigarette use is to depress smoking cessation, and thus flavored e-cigarettes do not increase likelihood of cigarette cessation. Moreover, adults **don't need e-cigarettes to stop smoking** conventional cigarettes. There are numerous studies showing that nicotine replacement therapy, cognitive behavioral or other therapy, and other non-electronic cigarette cessation techniques are effective. If Juul or other e-cigarette companies really wanted a device that would help adults quit smoking, they would have made them only in tobacco flavor, would not have made them small and sleek so youth can hide their use, and would have a step-down nicotine plan whereby people can titrate down the amount of nicotine they use.

Further Evidence of Immediacy of the e-cigarette Problem: Requests for Education, Prevention, and Cessation across the US

I am the Founder and Executive Director of the Tobacco Prevention Toolkit, an online, free set of curriculums and materials for educators and parents to use with middle and high school students to prevent and reduce youth use of all tobacco products. We have an entire section of the Toolkit just on e-cigarettes. The Toolkit was

⁴³ Gorukanti A, Delucchi K, Ling P, Fisher-Travis R, Halpern-Felsher B. Adolescents' attitudes towards e-cigarette ingredients, safety, addictive properties, social norms, and regulation. *Preventive medicine*. 2017;94:65-71

launched in September 2016. We receive **daily** requests for more information about our Toolkit, and in particular our e-cigarette and Juul prevention curriculum. Schools are aware of the e-cigarette and in particular Juul use epidemic in their schools and are frantically trying to find ways to help prevent and reduce such use in their schools and communities.

Schools are spending an enormous amount of time, money, and resources directly related to the e-cigarette epidemic. Schools have served as an effective venue for the delivery of drug education and awareness programming. Drug treatment services, however, are not commonly provided at schools due to legal and/or staffing constraints. Schools and parents need resources, funding, and immediate action. Many schools don't have a nurse or counselor on site to help with students caught vaping or needing help stopping their addiction. Further, many students don't have adequate access to health care or treatment aids including medication, and schools don't have the resources or feel comfortable intervening between parents and their children. Further, we have NO data to inform e-cigarette cessation for youth. Currently there are no nicotine replacement therapies (NRT) or other medicines approved by the FDA for use with anyone under the age of 18. While many healthcare providers are nevertheless prescribing NRTs, clinicians lack guidance on the NRT dosage to provide; this gap is especially salient if you consider the extreme amount of nicotine in a Juul pod or other pod-based e-cigarettes. The need to provide students, schools, and parents with education, prevention, and cessation resources is immediate and critical.

As evidence of the dramatic increase in requests by schools for e-cigarette and in particular Juul-related prevention education, in 2018 we conducted 28 educator

trainings across the US, with 730 educators trained. In just the first 9 months of 2019, we have already conducted 38 trainings across the US, and trained over 1,300 educators. In total, we have reached over **1,133,884 youth**.

Summary, Conclusions, and Policy Needs. In sum, the evidence is clear. Youth are using e-cigarettes, including Juul and other pod-based products, in record numbers. The increase in use of e-cigarettes is undermining and repealing the great progress that has been made by tobacco control efforts over the past two decades. Such increases in e-cigarette use come at a time when youth have negative views of cigarettes, and were unlikely to have initiated nicotine use with cigarettes.⁴⁴ **Immediate efforts are needed to reduce the epidemic of youth e-cigarette use.** Several **actions** should be considered, including raising the purchase age to 21, eliminating access to flavored tobacco products, and raising taxes to ensure that e-cigarette devices and e-liquids have the same price point as other tobacco products. We also need to enact a nicotine standard that applies to e-cigarettes (and all tobacco products). In the US, there is no maximum amount, concentration, or percentage of nicotine that can be in a tobacco product. Allowing a single tobacco product that has the amount of nicotine found in 1.5 to 2 packs of cigarettes is unacceptable, especially when the formula of the nicotine is easier to inhale and absorb. If e-cigarette companies want to propose higher levels of nicotine, they can be then used in prescription form, after the companies apply for and receive FDA authorization to be sold as cessation (drug) products. There is also an urgent need for education, prevention, and cessation programs. We have an

⁴⁴ McKelvey, K. & Halpern-Felsher, BL. Adolescent cigarette-smoking perceptions and behavior: Tobacco control gains and gaps amidst the rapidly expanding tobacco market 2001-2015. *Journal of Adolescent Health*. 2017 Feb;60(2):226-228. PMID: 27939880.

unprecedented number of youth addicted to nicotine through e-cigarette use, with no evidence-based medicine or guidelines for nicotine replacement therapy, behavioral therapies, or other help to provide schools, healthcare providers, educators, or youth. There is a real need for increased tobacco control program funding to fight the youth e-cigarette epidemic generally, but also to provide more education, prevention, and cessation services in schools. It is important to note that such education, prevention, and cessation programs should NOT be conducted by the tobacco/e-cigarette companies. There has been a history of these companies providing ineffective and often inappropriate, misleading, and harmful messages to youth.⁴⁵

Other solutions to the youth e-cigarette epidemic for which the FDA or other governmental agencies have authority include: prohibiting the online marketing and advertisements of e-cigarettes including prohibiting celebrity sponsorships and sponsorships at sporting and music events, where youth attend; prohibiting coupons and other promotional materials;⁴⁶ and regulating the design of e-cigarettes so they are less appealing to youth. It is also important that the FDA not allow any claims made that e-cigarettes are safe or less harmful than cigarettes, and that all e-cigarettes be pulled from the market until they have received pre-marketing authorization from the FDA. The FDA has the authority to do these actions now.

Thank you.

⁴⁵ Liu, J. & H-F, B. *The Juul Curriculum is Not the Jewel of Tobacco Prevention-Curriculum*. Journal of Adolescent Health, 63, 527-528, 2018. PMID 30348276

⁴⁶ Magid, H., Bradshaw, P.T., Ling, P. and **Halpern-Felsher, B.** Ownership of promotional materials predicts initiation of alternative tobacco products used among adolescents and young adults. JAMA Network Open. 2019 May 03;2(5):e194006. PMID: 31099874

Ms. DELAURO. Thank you.

Let me now recognize Ms. Berkman, and your full testimony will be entered into the hearing record, and you are recognized for 5 minutes.

Thank you for being here.

Ms. BERKMAN. Thank you. Thank you so much for having me, Chairwoman DeLauro, Chairwoman Lowey, Ranking Member Cole, and other distinguished members of this committee.

My name is Meredith Berkman, and I am a co-founder of Parents Against Vaping E-cigarettes, PAVe, a national grassroots advocacy group founded by three concerned moms as a response to the youth vaping epidemic, and as we all know, this is the most serious adolescent public health crisis our country has faced in decades.

We have all heard the staggering latest Federal figures—5 million teens vaping, a 135 percent increase in over 2 years in youth use, 1 out of every 4 high school students. It is the eternal kid exaggeration, the proverbial “Everybody is doing it.” But sadly, this time, it is more or less true.

FDA allowed flavored e-cigs like Juul, especially Juul, to remain on the market, even until today, without undergoing full regulatory review. These products we know contain enormous amounts of nicotine that harm our kids’ developing brains, and they are a toxic cocktail of known toxins, degraded metals from the devices themselves, and unknown toxins in the proprietary flavors. So we really have no idea what millions of our kids have been pulling so deeply into their precious developing lungs all day long and all night long, 24/7. In some cases, kids have been doing this for years.

The current outbreak of vaping-linked pulmonary illness is terrifying. But really, it is not surprising.

Now I am not a doctor. I am not a public health expert, but I am a volunteer parent advocate. And we know that these symptoms have been going on for years because we hear about them. And so the underlying crisis is the youth vaping epidemic that has harmed so many kids across the country and ended the lives of so many families, of entire families.

I want to very briefly share with you my story, the reason that I am sitting here today. In April of 2018, one night my son Caleb, then 16, came home and said, “Mom, Dad”—Dad is over my shoulder—“I want to talk to you.” And if you are a parent of teenagers, as I am with four of them, you know you never hear that. And so when you do, you listen.

And my son began to tell us about what he referred to as a very confusing e-cigarette presentation that he had heard at school that day, given by a speaker who was brought in through an outside anti-addiction group. When the teachers were out of the room, the educator repeatedly told the ninth graders that while Juul was intended for adults, it was “totally safe” and that the FDA would be approving this product any moment. Both things are untrue.

At the end of the talk, my son went up to the speaker, who—to ask more questions. He took out his Juul, showed my son and his friends how it worked, and referred to it as “the iPhone of vapes.” It turns out he was a Juul rep and that the school had no idea.

It was the realization that Juul was blatantly going after kids in their own schools, in their safe haven, that motivated me and my friends to take action, and we learned more and more about the predatory practices of Juul in particular, but others as well. The use of flavors, always flavors. Young-looking influencers. Targeted social media marketing done in places where we adults, we parents, we teachers were not going. And that is why we started our group.

Since then, we have gone national with our PAVe pods, an intended pun on Juul's flavored pods, in more than a dozen States and growing, including States like New York, California, Illinois, Kansas, Maryland, New Jersey, and Massachusetts. But we are getting bigger because we represent a movement, a growing army of volunteer advocates. Motivated "momvocates," I like to say, though also some dads, of course, fighting to protect our kids from these tech-chic, stealth by design, flavored vapes, the latest incarnation of big tobacco.

Some of these companies are so brazen, they are marketing to kids on the Internet, on school websites like Quizlet. My seventh grader saw a vape ad on an app game that she and her friends like called Flippy Birds. But we cannot allow big tobacco to use our kids as human guinea pigs. We know we are in a race against time, as I am now, on multiple levels, and so I very briefly want to say we need help.

We want to partner with the CDC. We want to partner with you. There is a huge disconnect between what the public understands and knows and what—the important work of the CDC, in coordination with the FDA. There should be an interagency task force, not just a CDC task force. There should be a central reporting portal. There should be a central information portal—VapingIllness.gov.

There must be a massive social media marketing campaign that is the opposite of what Juul and its copycats did, right? A media campaign that uses influencers, the Surgeon General, and athletes and celebrities that tells kids and their parents that this is the emergency. Yes, God forbid more people will die, and more people will get sick, but we all must have known this was coming.

And now it is here, and if we don't solve the problem now, we will have, as everyone has said, an entire generation of nicotine addicts or worse. We need your help. We need more funding and more education, more prevention work.

Thank you so much.

[The information follows:]

House Appropriations Subcommittee on
Labor, Health and Human Services, Education, and Related Agencies

“E-Cigarettes: An Emerging Threat to Public Health”

Written Testimony of
Meredith Berkman
Co-Founder
Parents Against Vaping e-cigarettes (PAVe)

Rayburn House Office Building Room 2358-C
Washington, DC
October 16, 2019

Good morning Chair DeLauro, Ranking Member Cole, and other distinguished members of the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies.

My name is Meredith Berkman and I am here as a co-founder of Parents Against Vaping E-cigarettes, PAVE, a grassroots advocacy group founded in April 2018 by three concerned moms as a response to the youth vaping epidemic, the most serious adolescent public-health crisis our country has faced in decades.

We have all heard the staggering figures: 5 million teens are vaping, a 135% increase in youth use over two years. 1 out of every 4 high-school kids. It's the eternal exaggeration, the proverbial "everybody's doing it" but this time, it's more or less true.

It should never have happened. But it did. FDA allowed flavored e-cigs like JUUL—especially JUUL—to remain on the market, even until today, without undergoing a full regulatory review. We already know that these flavored vapes contain enormous amounts of nicotine that harm the developing brain, causing cognitive change and opening pathways to further addiction. Since e-cig flavors are proprietary, we still have no idea exactly what's in that heated toxic brew that millions of young people are pulling deep into their developing lungs dozens of times a day, in some cases for years.

The current outbreak of vaping-linked lung illness is terrifying but in retrospect perhaps not completely surprising. The outbreak whose cause has yet to be determined is, in fact, a symptom of the underlying crisis, the vaping epidemic itself that has harmed so many kids and upended the lives of so many families.

But I want to back up for a moment and share with you my own story, the reason that I am sitting here today testifying about vaping before a House subcommittee for the second time in six months. Earlier this morning my co-founder

Dorian Fuhrman was also a witness, speaking about PAVE and our work before an Energy and Commerce subcommittee. I could never have imagined any of this—nor would I have wanted to: I am an accidental public-health advocate, a MOMvocate, and none of this was ever part of the plan.

In fact, I have been a stay-at-home mom for many years, raising four kids—ranging in age from 19 to 12—and actively volunteering in their schools and in our community. But all of that changed on the evening of April 3, 2018 when my son Caleb, then 16, came home and said, “Mom, Dad—I want to talk to you.” If you are a parent of teenagers you know that never happens. And so my husband Daniel and I listened closely as Caleb began to tell us about a “confusing” e-cigarette presentation that he’d heard at school that day, given to the 9th grade by an anti-drug speaker brought in through an anti-addiction group.

Caleb described how this supposed educator told the class when the teachers and administrators were out of the room—a common practice for these talks—that JUUL was intended solely for adult use. Yet in the next breath, he told Caleb and his friends, who had started using JUUL, that it was “totally safe” and that the FDA would be approving the device any day—both things untrue.

At the end of the talk, Caleb and Dorian’s son Phillip approached the speaker to ask more questions. At that time, this adult took out his JUUL, showed the boys how it worked, and referred to it as the “iphone of vapes”.

We quickly discovered that the speaker was a JUUL rep; that Caleb’s school had no idea; and that an employee at the outside group had naively asked JUUL’s youth prevention education coordinator—a position no longer listed on the company’s website—for speaker suggestions.

The realization that JUUL was blatantly going into schools—something we discovered the company was doing in other states, where it was offering grants to districts that would accept its “curriculum”—forced us into action. We started researching JUUL and vaping in general late at night when our kids were asleep, and the more we learned the more determined we were to join forces with the vaping version of MADD—Mothers Against Drunk Driving. But such a group did not yet exist because the crisis was moving so quickly and unfolding in real time.

And that’s why we started PAVe.

Since then, our organization—originally intended as an on-line resource for parents who want to educate themselves about vaping—has gone national to meet the enormous demand from those seeking resources for their JUUL-dependent, nicotine-addicted kids. But there aren’t many. In fact, there is still no FDA-approved treatment for this problem.

We now have PAVe “pods”, as we call them, an intended pun on JUUL’s flavored pods, across the country including in states like New York, California, Illinois, Kansas, Maryland, New Jersey and Massachusetts.

And more importantly, we are creating a movement. We are a growing army of volunteer advocates—motivated MOMvocates—fighting to protect our kids from the predatory practices of flavored e-cigarette companies like JUUL. Through the use of flavors and targeted social-media marketing, JUUL convinced our kids that its tech-chic, stealth-by-design device was essential to a cool lifestyle.

What JUUL never said—and what the kids did not understand—is that the lifestyle JUUL was actually promoting with its fun flavors was nicotine addiction. And thanks to its patented nicotine-salt technology, and enormous amounts of nicotine—as

much in one flavored pod as in an entire package of cigarettes—JUUL successfully disrupted the entire e-cigarette market and seduced a generation of teens.

When JUUL got called out for creating the youth epidemic, it announced it was done with social media and quickly “made the switch” to an adult-focused ad campaign. Then it turned out those ads contained unsubstantiated health claims. Now JUUL’s not advertising in the US at all.

Claiming that it was “sensitive” to concerns about youth and flavors—well-founded concerns since research has proven that flavors hook kids—announced last November it would no longer sell retailers flavors like mango, crème, and fruit. Yet almost a year later, these flavors are still being sold in many vape shops and convenience stores all over the country. We know this because we have seen it ourselves and because parents report it to us this all the time. And by the way, JUUL exempted from this “self-regulation” its mint and menthol flavors that are teen favorites and are responsible for more than 70% of the company’s sales.

Meanwhile, JUUL copycats have continued to flood the market—still not fully regulated—with flavored vapes containing even more nicotine than JUUL. There’s EonSmoke, whose sweet flavors include pink-lemonade. The tropical mango Stig, a disposable vape so small it can fit in a child’s hand. Suorin’s products can easily be mistaken for a highlighter pen.

Some of these companies are so brazenly marketing to kids that they advertise on student homework websites like Quizlet used by middle-schoolers. My youngest, who’s in 7th grade, even saw a vape ad recently on a digital game she and her friends like called “Flippy Bird.”

But we MOMvocates won't allow Big Tobacco 2.0—new look, but original playbook—to use our kids as human guinea pigs for the e-cigarette experiment. Even JUUL's former CEO—recently replaced by an Altria apparatchik—admitted publicly that his company had no idea of JUUL's long-term effects. Haven't we already seen enough?

We are grateful that the president has promised that FDA will finally use its full authority to remove all e-cig flavors including mint and menthol from the market; we hope he fulfills that important promise immediately. We are not prohibitionist, and agree that tobacco flavor should remain available for adults.

No matter what, PAVE, along with our many partners in the anti-tobacco coalition, will continue pushing for flavor-ban legislation on the local, state, and national levels. That way, if and when JUUL and others slither their way back through FDA's regulatory process, these flavored products will not be available to our kids.

We are in a race against time on multiple levels. I urge the members of this subcommittee to provide much-needed additional support for the CDC as it struggles to solve the mystery of the vaping-linked lung illness and faces an enormous challenge that may take years to untangle: providing support for potentially millions of teens who are already addicted to nicotine.

Ms. DELAURO. Thank you all very, very much for very compelling testimony.

Before I ask a couple of questions, I just want you to know that we are trying to move here. The Judiciary Committee just passed, I mentioned earlier, a piece of legislation that I have been pushing over the years is Preventing Online Sales of E-cigarettes to Children Act, and they did it by voice vote. That means that we have got bipartisan support for this—for this effort.

So thank you for your advocacy in these areas.

Commissioner, let me ask you these questions. You have talked about the rising rates in Connecticut, went through all of that, and that e-cigarettes are now the most common form of tobacco amongst high schoolers. How is it impacting public health in Connecticut? How does it impact the schools?

And if you can then just mention the challenges that you face while you are investigating the outbreak and how you collaborate with CDC, Federal partners, and what additional resources do you need?

Ms. COLEMAN-MITCHELL. It is a loaded question, but I will attempt to make sure I answer it to the best of my ability. [Laughter.]

Ms. DELAURO. You can do it.

Ms. COLEMAN-MITCHELL. I have to say that, as I shared in my testimony, that it takes a number of resources from varying sections within the department. I shared that our tobacco program, you know, our infectious disease, our State lab, these are individuals that are working on—tirelessly, right, on all different types of public health matters. And then we pull them together to say here we have now vaping-related lung diseases, and it is just the resources are very scarce in regards to staff resources and funding.

Right now, in Connecticut, our tobacco prevention program has been level funded at about \$874,000, and then we get an additional pot, which comes up to be about \$1,000,000. That is a staff of about four people who really are spread quite thin throughout the State to really focus on working with colleges and universities and having the “train the trainer” aspect of working with schools, high schoolers, in terms of training them.

Also with the colleges, we are trying now to have counseling done because it is so pervasive on college campuses. And then we also have trainings and we have education, we have campaigns, but it is just scarcity. You know, Connecticut is a small State. But in essence, it really is not making the messaging that we want and need across the entire State to reach our young people. It is very limited.

Ms. DELAURO. What is the impact on schools?

Ms. COLEMAN-MITCHELL. As it was eloquently shared, it is tremendous. I mean, you have people that are starting as young as 13 and 14. Let me just share a quick story.

On my way here, I was in the car with a guy who was my Uber driver, and he asked me what I did, and I shared it. And I knew when I got in the car, I smelled smoke. Clean car, but I smelled it.

And he says, “You know, I smoke.” And I said, “I know. I smell it.” And he says, “But I am going to tell you something. I tried to

quit." And he is an adult, and he says, "I started when I was 14." And I said, "What was it?" And he said peer, peer pressure.

He went ice skating. Now this—and he said to me, "This is the dumbest thing that I thought of." And he said, "I thought that—we thought smoking would keep us warm for ice skating," and he said, "But I loved it. And from that moment on, I smoked and smoked and smoked."

He is 70 years old. He tried to quit many times. He used Juul. He put out \$120, he said. He said it burned his lungs. It hurt him to inhale. He threw all of that out, and he says, and he is still smoking.

So what I am saying to you is that it is starting at a very young age. It is starting with all of the peers. And one of the best approaches that we can take, as public health has seen over and over again, is that peer approach. When we put together that Tobacco 21 legislation, effective October 1st, it was beautiful. Not because all the legislators or that myself as a commissioner, you have governors, and everybody was there. It was beautifully said.

But when that young lady who was a high schooler stood up and said that she had three of her friends that were hospitalized and one remaining friends who was hooked up to tubes in the hospital as she was standing there speaking to us, what did I see sitting up front? Every single one of those young people leaned forward and listened.

That is the impact that we have to have because people, young people truly, honestly believe it is a safe practice. We have to continue to educate, educate, educate. That is the challenge.

Ms. DELAURO. I have time remaining, but let me yield to Congressman Cole.

Mr. COLE. Well, first of all, I want to thank each of you for your testimony. It is incredibly helpful, and I think there is no question we clearly need to educate lots of folks about the dangers involved here. And you being here is part of that education process. So thank you.

I think your advocacy will probably make a difference, already has, as my good friend the chair has put additional resources behind these kinds of efforts. And that will be an interesting discussion we have with our colleagues in the Senate.

Ms. DELAURO. On the Senate side.

Mr. COLE. You know, because I think you are on the side of the angels here, Madam Chair.

But, you know, I do have some concerns, and so let me start with you, Dr. Satel. We have had efforts to ban, entire bans, outright of e-cigarettes. And I think we would all say, gosh, we are extremely worried about this youth epidemic, but how have those bans worked? What have been the consequences of them? It has been relatively recent, so you may not have any data.

Dr. SATEL. Are you referring to the ones that have just been announced since September?

Mr. COLE. Yes, I mean, do you have an opinion about them, whether or not that is a good approach?

Ms. DELAURO. Use your microphone.

Dr. SATEL. Well, I do know that vape shops have reported an incredible decrease in people who are patronizing them, and that is

the thing to worry about, of course, is if—you know, in the case of e-cigarettes, in the case of harm reduction, and this is, basically, we are talking about people who are addicted to nicotine, just as if we were in a way talking about people addicted to opiates.

We deal with people with opioid addiction. We have methadone. We have needle exchange. These are risky behaviors, but we try to mitigate the risk. And that is what an e-cigarette device is for smokers. It is an attempt at risk mitigation.

So the question is, and I have worked in methadone clinics my professional life. The question with addiction is always compared to what? And so if it is e-cigarettes as opposed to smoking because a person has failed patches and gums and all the conventional ways of quitting, then that is an infinite benefit.

Again, are these devices safe? No one would say that. And should they ever be used by nonsmoking teens? Never.

Mr. COLE. That is, I think, a very important point. Let me ask you this. You mentioned in your testimony the experience of the United Kingdom. Did they have the same explosion among youth that we clearly have in this country?

Dr. SATEL. They don't seem to, and it is an interesting question. And the UK has had a long record of harm reduction. In fact, they legalized heroin back in the '20s, and Michael Russell was one of their most—kind of the godfather of smoking harm reduction. He always said people smoke for the nicotine because it is addictive, but they die from the tar.

And Public Health England, which is their equivalent of our CDC, the Royal College of Physicians, they have all endorsed vaping as an alternative for smokers who can't quit any other way, and they have based it on research. And I certainly can provide all that.

Mr. COLE. Yes. Well, I am curious what they are doing on the marketing angle. I mean, you have all mentioned about marketing and targeting, and that is clearly a big problem here. And clearly, targeting toward an uneducated audience of young people in very duplicitous and septic way.

Do they have a problem in that, or they have some set of—I am looking, I guess, for a regulatory scheme that gets us a better outcome than we have got here because there is no question we have this explosion amongst young people that really is concerning.

Dr. SATEL. It is interesting to think of the comparative approaches, and I don't know how they advertise to kids—or not advertise to kids, of course, but how their advertising could be mistaken to be attractive to, you know, teens. That, I don't know.

But, but what is so important about their approach, again, is that they—is that their—forgive me. I sort of forgot my point for a moment. Well, maybe ask me another question, and it will occur to me. It just slipped my mind.

Mr. COLE. I don't have much time. I will just end with this.

Dr. SATEL. OK.

Mr. COLE. That is what I am looking for is something we could do that would stop the epidemic or start educating people. At the same time, look, I have had constituents that were lifelong smokers that have told me, please, this is how I got off cigarettes. Don't put me back on it.

Now they are a smaller part of the audience, and sometimes we are in the business of comparative goods and who is most at risk and that sort of thing. So I am just trying to find if there are ways. We clearly have addiction problems, all sorts, in this country.

We are like 4-point—4 percent of the poor population use half the illegal drugs. I mean, this is like something in our DNA as a society at some level.

Dr. SATEL. Yes. Well, we can't forget the purview of public health is all vulnerable people, teens and adults. But I did remember my point, which is that—and this is so key to the UK, which is they have nationalized health. They don't have individual insurance. And that is why they are so invested in vaping because the cost savings to the government could be huge. And that is a big difference between here and there.

Mr. COLE. Interesting. Thank you, Madam Chair. Appreciate that. Appreciate this hearing very much.

Ms. DELAURO. Thank you. Congresswoman Roybal-Allard.

Ms. ROYBAL-ALLARD. Since the United Kingdom has been mentioned, since the 2016 Royal College of Physicians report endorsing e-cigarettes as 95 percent less harmful than the combustible tobacco-containing kind, many in this country and in Congress have used harm reduction as an argument to oppose any Government regulation of e-cigarettes.

However, that same year, the American Medical Association, the American Thoracic Society, the American Academy of Pediatrics, and 10 other medical organizations sent a letter to Congress that explains why they believe currently available data does not support the use of e-cigarette products as a smoking cessation strategy.

Dr. Halpern, can you provide some clarity to counteract this harm reduction argument, and has any e-cigarette been found by the FDA to be safe and effective in helping smokers quit?

Ms. HALPERN-FELSHER. Thank you for asking that question. It is a good one.

There has been a profound difference between what the UK data say and what our U.S. data are saying, and part of it has to do with science, has to do with the methods that are behind this. A lot of it also has to do with and in response to some of what we were hearing earlier, has to do with the marketing.

In the UK, we don't have—they don't have the marketing to youth that we have seen here in the U.S. It doesn't exist. Also, their e-cigarette products are different. They have a nicotine standard, where they have no more than 20 milligrams of nicotine in any given product. So they also just have different products, and they don't see it.

They have started off all along saying that it is a device for quitting, whereas in the U.S., that was not the original message. The original message was more to be a youth product. So that is one of the big differences there.

In terms of do we have any safe products? No. As of now, we have no products, no e-cigarette products that have been submitted for premarket authorization to the FDA, nor do we have any products that have been submitted as a cessation tool.

Whereas in contrast, we do have products that are very effective in helping adults quit smoking, like nicotine replacement therapies,

other medicines, cognitive behavioral therapy, and so on. So those are definitely more and have been approved, whereas e-cigarettes have not.

Ms. ROYBAL-ALLARD. I passed a bill known as the STOP Act that was directed at educating parents about the dangers of underage drinking. And this national media campaign has actually helped to reduce underage drinking in this country. Would you suggest or what are your ideas in terms of having a similar national campaign to educate parents about the dangers of vaping?

Ms. HALPERN-FELSHER. For me? I think it would be a very good idea to have such. I go around the country, and Meredith and I team up on some of this work, to give talks to parents throughout the country. But I will also say that—but I will also say that, yes, we do need to educate parents.

In our toolkit, some of our materials on there do educate parents, where we have information about how it is hidden in plain sight and how easy it is—or how hard it is to spot these products and what parents need to be doing. But we also really do need national campaigns and information and help that go directly to schools, to healthcare providers, and to youth themselves.

Parents, absolutely. But it is a bigger issue than just parents right now. And youth also in schools 8 hours a day, we need to really target schools as well and helping them.

Ms. ROYBAL-ALLARD. Ms. Berkman, your view?

Ms. BERKMAN. Yes, thank you.

I think there—again, I said this earlier. There is an enormous disconnect between all of the important work. I mean, we know that CDC is working 24/7, but we also see education as a very important form of advocacy, and we are lucky enough to share some—Bonnie shares some of her resources with us. We give a lot of parent presentations, and it is shocking to me that just the other day, we spoke at I think it is the largest public high school in New York, and there were parents who were shocked by the information we were giving.

You know, we are all so deeply in this. But I also think there is an enormous disconnect between also public health providers, and I will give you an example that terrifies me.

Over the weekend, I mean, we have parents who reach out to us all the time, and sometimes I carry these emails where people spend you can see, you know, 45 minutes pouring out their hearts. You know, my child was en route to be recruited as a star athlete in college, and now he can't even run a mile.

Or I had an easygoing kid who is having bouts of extreme anger. Or I have a kid who was a great tennis player. Now he has restrictive lung disease. Things that have been brewing for some time.

But a woman reached out to us over the weekend in a panic, and she just sent it to our regular info line. And she said, "I am in the hospital now with my child. We were here before a few weeks ago. She was in the pediatric ICU. She was sent home. Now we are back again."

"I am terrified," she wrote to us, "that the doctors here—" And I won't say where she is from to protect her privacy, but a small town out West. She said, "The doctors really don't know enough. How can you help me?"

And we immediately wrote back to her and saying, you know, where are you? What hospital? And we didn't hear back from her again.

And those kinds of stories are so common, and they are haunting. That is a parent who found us online who may not have thought to go to, you know, a CDC reporting portal or an FDA reporting portal. But she looked up parents, and her feeling, and we hear this a lot, is that the doctors in some places still don't know. We find that shocking, but it is true.

I just want to make one other point, if I may? There has been so much talk about this outbreak and THC. But if you look a little more closely at the CDC's own numbers, when they say that 76 percent of cases are people who were using THC, that is not THC exclusively. Only 32 percent were using THC exclusively. Of the 58 percent who said they were using nicotine not exclusively, 13 percent.

But if you just focus on this as a THC crisis, it is an enormous mistake. This is a crisis of an entire generation of kids who are vaping, who have been having these symptoms for, in some cases, years. And the numbers we have are so important, but we need to get a—I don't know what it is called because I am not a public health commissioner or expert—but a population surveillance study that shows us what the symptoms are.

Because if we don't start recording—we talked a lot about the data, the recording, the modernization. If you don't start recording the symptoms of these 5 million kids, then we are going to have an even bigger problem for even more years.

And again, I am not a public health expert, but we hear from parents—hundreds and hundreds of parents—who are so frightened, who see changes in their kids physically and emotionally, and they are terrified, and there is a disconnect. We need more education. We need more social media for kids and parents and doctors and everyone.

Thank you.

Ms. DELAURO. Did you want to comment?

Ms. COLEMAN-MITCHELL. Yes, I did. I just want to support what was just being said. It is extremely important. At the State health department, we have, again, many resources. The interesting thing is that I had to go about making it a reportable disease so that we could get a handle on what was going on. And that was just the beginning.

We have surrounding neighboring States that we are working with and trying to find out what is going on there. And then that linkage to CDC, it is incumbent upon looking at how do we get additional funding and resources to really tie into a true data surveillance system that not just for this, because there will be other public health concerns that come about. But this is one clear example because of the loss of our young people and the addiction that we see, that we really do need funding to support a true surveillance system that is at a State—at a local, a State, and a Federal level that is totally connected. Absolutely.

Ms. DELAURO. Thank you. Dr. Halpern-Felsher.

Ms. HALPERN-FELSHER. Thank you. If I may, two more quick follow-up points on this very important conversation.

First, when we are talking about funding for research. We really need to understand the nicotine levels that are in these products. You are hearing just today in the span of an hour differences between a pack of nicotine—a pack of cigarettes' worth of nicotine and two. And I have never seen public health experts on the same side confused.

We need research to understand that why, similar to Meredith, I get called constantly by healthcare providers, saying how much nicotine replacement do I give? Not only is it not approved by the FDA to give this for those under 18, we know it is. We know that it is being used off label. My adolescent medicine doc friends are using it all the time, but how much?

Do you give one patch, which is 20 milligrams of nicotine? Do you give one and a half? Do you give two to match that 41? We don't know, and we really need the research to be able to inform healthcare providers.

Second, we also need the research and the surveillance and the information to inform schools once again. Because I get principals all the time who say I am so tired of busting kids. I don't even want to go into the bathroom anymore because then I am spending the entire day filling out paperwork, and I actually have other things I need to be doing. So we also need information and research to really inform those constituents as well.

Thank you.

Ms. DELAURO. Thank you. It was a really great conversation. I don't know, Dr. Satel, if you would like to add anything here?

Dr. SATEL. I would. Just one point. E-cigarettes, again commercial nicotine vaping, which is regulated by the FDA, but none of the devices have been approved yet. Oh, yes, they have all had to submit their—

Ms. DELAURO. They have not. No, no—

Dr. SATEL. Okay. I am referring, though, to the PMTAs. No, those are due in May of this year.

Ms. DELAURO. May 2020. They are due.

Dr. SATEL. Yes. Well, the one just did submit last week. But yes, it is true they are not approved.

Ms. DELAURO. They are not approved.

Dr. SATEL. I agree with that. That is a fact. But they have been around for at least 10 years, and I don't disagree for a moment that if teens have tried them, I am sure some of them have had respiratory or one would cough, you know, feel some irritation the next day. Kids with asthma will have that exacerbated, no question about that.

But it hasn't been until this summer that we have seen these dramatic pulmonary complications. So that is also another bit of evidence, in addition to the basic epidemiologic tracking of, you know, what did these people use and what was in their blood and what was in their urine? And have they taken lung biopsies?

But the point is that this makes—this is more suggestive evidence that what we're seeing is the illicit cannabis products or illicit nicotine products. They are out there, and those should be—those aren't permissible either.

Ms. DELAURO. It is obviously a great topic and various points of view, and making the case. But it would also seem that—and one

of the points I will make is that we have no scientific data. I said at the opening in my statement are these products safe? Are they unsafe? How do we regulate them?

We have a regulatory agency that has abdicated its responsibility to regulate a product that we now find after 10 years, or whatever it is, is creating a public health crisis. So that, you know, we have the tool to address an issue that is a public health crisis. We are not using the tools, and we are being subjected, I will tell you, on the premarket review, we are now looking at an industry that is pushing back.

And as a question I have for you, Dr. Halpern-Felsher, is about mint and menthol because the industry is pushing back when the HHS has said no mint, no menthol, no flavors, and they want to exempt mint and menthol. This is a moneymaking proposition for a tobacco industry. That is what is at the center of this effort.

Let me ask you, Doctor. Flavors—mint, menthol—attractive to kids who would not normally smoke tobacco products?

Ms. HALPERN-FELSHER. Absolutely, yes. No doubt about it. In our own data, we are showing that at least 30 percent of youth who are using e-cigarettes started and continue to use with mint and/or menthol. And that is true not just with e-cigarettes, but across all tobacco flavors, and our latest publication shows that.

And we talk to youth, and they will say absolutely “I love mint. I love menthol. That is what I am using.”

Ms. DELAURO. Let me ask you this. Your response to those who say these flavors are needed for adult smokers?

Ms. HALPERN-FELSHER. I would say there is no evidence, and I would say that even if you like these flavors, I would—you don’t do that on the backs of youth. And not only that, as I said before, we have other ways for adults to quit smoking conventional cigarettes that are proven, that are approved by the FDA, whereas e-cigarettes are not.

And if e-cigarette companies want to be approved and used by the—approved as a cessation device, then it is not just a premarket review, they need to go through CDER. So there is a much higher standard if they are going to be arguing to be a cessation device, and they have not gone through those proper channels.

Ms. DELAURO. And that is what the FDA should be doing in that regard there?

Ms. HALPERN-FELSHER. That is correct.

Ms. DELAURO. And the illegal—well, let us just talk about it because there are challenges on the marketing of these products. And there is a question across illegal marketing created the perception that the devices are safe. Let me just ask you, as a mom, do kids understand the risks involved?

Ms. BERKMAN. Even now, I think that they don’t. What is really scary is kids now want to—now that the kids are frightened, they realize what addiction is. They are terrified.

And my son comes home and says, “Mom, there is a boy at school. He wants—he is scared, he is afraid he is going to sick, but he doesn’t know how to stop. How do I—what do I tell him?” And I think we don’t have anything to tell him. They are addicts, and they don’t know it.

Ms. DELAURO. What is the marketing doing to kids?

Ms. HALPERN-FELSHER. So we have data on that as well and published. We are well aware of the fact that the marketing is influencing young people. We did a study looking at flavor ads, not Juul, but across the board flavor ads, and we asked adolescents are these ads targeting you, somebody older, somebody younger, because the e-cigarette market says they are targeting for adults.

Uniformly, the young people in our study said they are targeting me, maybe somebody slightly older—what kid doesn't want to be older—or slightly younger. Kids are not saying that they are targeting adults.

We also did a study that we published looking at adolescents' perceptions of what are really not allowed, cessation ads like quitting and switching. And uniformly, youth knew that those were cessation ads, and those are implying if it is Okay for adults to use them to quit, they, therefore, must be safe.

So young people are not only attracted to the ads, they are being misled by the ads. And we have lots of papers that we published and others, some of which I provided in my written testimony, to show that adolescents are very much misperceiving the e-cigarettes, the products themselves, the harms, and the nicotine potential. Until recently, they were not aware and did not understand those terms.

Ms. DELAURO. Just—I just—there was one point that was made. Is it true that adults who are using the e-cigarettes are also using cigarettes as well, that they are dual use? Is that—am I wrong in that perception?

Dr. SATEL. You are not wrong.

Ms. DELAURO. That is right. So they do both?

Dr. SATEL. That is—

Ms. DELAURO. So it is not a question that if they have this, that they will go to cigarettes—

Dr. SATEL. Correct.

Ms. DELAURO [continuing]. They are dealing with cigarettes at the moment. The UK data, well, we can get back to that. Let me just, my colleague, let me just yield to my colleague from Oklahoma.

Mr. COLE. Thank you, Madam Chair.

Actually, I am going to yield to my friend from Maryland, if I may? I am going to have to leave shortly. I have got another appointment. But before I do, I just want to thank each of you. This has been an excellent, excellent hearing, and we appreciate the information you have brought to us.

There is a lot of areas of agreement here, quite frankly. Clearly, in terms of the youth epidemic. Clearly, in terms of advertising concerns. Some areas of disagreement, but not the kind that would keep us from making additional investments here and, frankly, I think finding hopefully a better regulatory scheme than we currently have because it doesn't seem to be getting the job done in terms of young people.

But that said, I will just yield the remainder of my time to my friend from Maryland.

Mr. HARRIS. Sure. Thank you very much.

Thank you, Madam Chair, and thank you. I am sorry I had to step out.

But this is obviously an important topic. Clearly, no one wants, you know, children to be exposed, develop habits that they shouldn't be developing. I think we have broad agreement on that. The question is how you go about doing that.

Because in the last panel, I think most of you were here, I mean, the bottom line is it is very hard to stop this leakage across age, and that is of a concern to me. Now I have a staff member in the District was a chain smoker, you know, I guess about 4 years ago started vaping, completely gave up combustible cigarettes.

Now I am convinced because I know, I talked to him. You know, he is the guy that had a chronic cough, things like that. None of that. I mean, I am convinced that his life span will be actually lengthened by this device. That being said, clearly, you know, if a 16-year-old decides that they are going to do this—and there is some evidence that more will decide to do this than smoke combustible cigarettes, that that is something we have to watch out for.

My concern is that throwing the baby out with the bath water. The bottom line is how do we preserve access to people for whom this is a very useful smoking cessation device. And look, we all have friends, we all have relatives, we have people who tried to stop smoking. They try the gum, and they try the patches. They try everything. Didn't work. And for some of them, e-cigarettes work. Vaping works.

So how do we do this, and how do we avoid—and Dr. Satel, let me ask you. How do we avoid—one of my concerns is that if we outlaw it, we are going to get black market stuff. And you know, the testimony from the CDC was just that this is actually the problem. The problem is if you don't make it available, if someone says, look, this person works for me. He says, look, I really want to stop smoking. He is going to go get a black market product, and that might be even more dangerous.

So how do we—how do we balance that? How do we come to the right conclusion?

Dr. SATEL. Well, I think there is no question you will get black market use. I mean, no question about that. The way to balance it is to preserve the flavors because, actually, there are data, are a number of studies that show how essential they are to adults, and they are in my testimony. But so very significant, that evidence that the flavors matter, that pulmonary function tests improve over time and blood pressure.

Now extrapolating that out, you would imagine life expectancy to be longer than if those people had continued to smoke, but we will have to follow them. The way to do it is to crack down much more—much more aggressively than we have been doing.

I know the FDA is working hard on this. I know Juul has a \$30,000,000 campaign. But the enforcement on selling, the enforcement on age verification and so on, even still the packaging and all this, even though I know the FDA is working on it, that just has to be tripled down on. There is no question about that, very important.

Someone mentioned before, though, I must say that puzzled as to why menthol and mint still occur. Well, the biggest consumers of those Kools and Newports actually are the African-American population, and I would worry again that they would go back to

their cigarettes because there is such a perversity in this issue. Cigarettes are legal, and now e-cigarettes are in danger.

You know, the device that can help people who fail those other options, which do have a pretty poor track record of working. And it is wonderful when they can. I would always recommend something you don't have to inhale to get off cigarettes, or cognitive behavioral therapy, they don't have to have nicotine at all. But some people just can't. It is a last resort for them.

And so these devices are so important, and flavors are so important to their effectiveness. So we have to preserve that for adults while beating every, you know, intervention we can targeted at preventing teen use.

Mr. HARRIS. Sure. No, thank you. And I will just ask generally, any of you can comment. You know, one of my concerns is that the lung injury is now connected to the use of THC because I think we sent a message to our children that, actually, marijuana is safe. I mean, we call it a medicine. I mean, aren't medicines safe?

How concerned are any of you that we are sending a message to children that marijuana is safe, and one thing we end up getting is this vaping problem that has resulted in very serious lung injury to young people?

Ms. BERKMAN. Dr. Harris, may I?

Mr. HARRIS. Yes, ma'am.

Ms. BERKMAN. First of all, I think you were out of the room earlier, you know, if you look at the CDC's own figures about why everyone keeps saying that this is just about THC, it is not correct. Because 76 percent of the people who have had these issues were using THC not exclusively, and I haven't seen the breakdown that says if all 76 percent were using THC and nicotine. Because it is 32 percent are only using THC, but 76 percent say THC and nicotine and perhaps other things. I would have to look at those numbers.

This is not just about THC, and I know this because if these kids are using THC in vapes, and I think we know from the research that many of them are, these kids, so many of them, started with nicotine. They likely started with Juul, right? That was the market disrupter.

Nicotine, it has long been known and long been proven by scientists—now I am not a doctor, I am not a scientist, but I have also reach research. Nicotine is a gateway drug. Nicotine opens pathways for further addiction.

So unless these kids are being—these patients are being asked what did you start with, we really will never know. This is about the youth vaping epidemic. This terrible outbreak is an outgrowth of the underlying epidemic that FDA failed to fully regulate these products, that we as a society allowed a company like Juul, worth \$38,000,000,000 before maybe the last couple of months since valuation was affected, to go into my child's school, to go into other schools, to use influencers and the flavors.

We should talk about harm introduction, rather than harm reduction. We are talking about a generation of kids we all know who would otherwise not have been initiated into tobacco use in such enormous numbers.

Mr. HARRIS. No, I understand that. My only point is that I am going to disagree with you. I think there is actually a close link between THC use because if you look at the number of people who have this disease who said they used THC versus the number of people who vape and have not used THC, the discrepancy explains that there is a clear association.

Just so everybody else understands, I mean, you are not saying there is no association?

Ms. BERKMAN. I am not saying there is no association—

Mr. HARRIS. Thank you very much. Thank you.

Ms. BERKMAN [continuing]. But there is no answer about what the problem is.

You're welcome. Thank you.

Mr. HARRIS. Madam Chair, thank you.

Ms. DELAURO. Thank you. Yes, go ahead.

Ms. COLEMAN-MITCHELL. Actually, I wanted to follow up with a comment, one that was said earlier that will also reflect in responding to Congressman Harris.

The statement was made that we have just recently seen the impact of e-cigarettes and vaping. I will beg to differ. I will beg to differ to say that there have been situations where many people are now reflecting, saying that I have had respiratory distress, respiratory illness over a span of years. So it just not has happened this year that we are now seeing the skyrocketing.

The unfortunate thing is that people were thinking that it could be the environment. It could be an environmental issue. But the bottom line is that it still goes back to support of having some type of surveillance system in place so that we can comparatively collect data and look at what is happening.

I will secondly say that the black market exists. Let us just be honest. It exists. It is going to exist. And there is an underground that is pervasive to our young people that is so attractive to them. It is intentionally attractive to them.

So we would be remiss—and I come from strictly a public health perspective. We would be remiss if we did not do something in regards to overall population health, in regards to addressing nicotine and its effect and this addictive behaviors that it has on people. But at the same time, we need to do something, period, in regards to the impact that it is having on our young people.

And why? Because they are getting hooked at a very early age, which makes it difficult for them to somehow cease, stop using these particular products, and they go on, as it has been said, to use other products.

And we are going to end up, as I said earlier—and you weren't here to hear this—with a nation of a whole generation that has perished or have severe chronic illness that will impact our healthcare cost tremendously. But besides that, it is going to impact quality of life. And I also said ultimately death, which you have already seen.

Ms. DELAURO. Go ahead. And then we will wrap it up.

Ms. HALPERN-FELSHER. Thank you.

I totally agree with that. And I just want to say also that when we are talking about research and we are talking about funding and regulation, it is not just the e-liquid that is in these. It is also

the device. And we are also seeing is that young people are taking the same devices that they became addicted with with nicotine, opening them up, whether it is Juul, which is a closed system, or the open system like the mods, opening them up and putting all the other products into it, such as marijuana.

So it is not just whether we are talking about nicotine e-cigarettes. It is a combination of the nicotine, the marijuana, and the vaping devices themselves that we need research on. And like was said earlier, I get calls from physicians for the last 3, 4 years saying that they are seeing vaping-related illnesses, pneumonia, asthma, that they can only trace back to e-cigarettes even before the current epidemic.

Ms. DELAURO. Well, first of all, let me just say, as my colleague Congressman Cole pointed out, this has been an extraordinary hearing, starting with Dr. Schuchat at CDC and what they are engaged and involved in. And with all of you and the richness of the information about what has struck us, and it has its roots years and years ago, but it is now here full blown.

And I will go back to the principle that I started with on this because it was the Congress that gave the authority to the FDA to look at all tobacco products, including e-cigarettes. The FDA—and I will continue to repeat—prior administration and in this administration abdicated the responsibility of looking at the safety of this product that now is on the market, that is sweeping the country, that has created an increase with young people that is of epidemic proportion, as we hear.

And now we see that the result is of serious illness, lung injury, and even death. And we have at the moment no data from which to go with. You can talk about each of the pieces, the increase in the vaping by youngsters. You could talk about the illness. But unless we address the fundamental issue, we really are not going to get to the bottom of this.

I would like to ask unanimous consent to enter into the hearing record a letter from N-A-C-C-H-O, NACCHO. And hearing none, no—so ordered.

[The information follows:]

NACCHO

National Association of County & City Health Officials

The National Connection for Local Public Health

October 15, 2019

The Honorable Rosa DeLauro
Chair
House Appropriations Committee
Labor, Health & Human Services,
and Education Subcommittee
Washington, DC 20515

The Honorable Tom Cole
Ranking Member
House Appropriations Committee
Labor, Health and Human Services,
and Education Subcommittee
Washington, DC 20515

Dear Chairwoman DeLauro and Ranking Member Cole:

On behalf of the National Association of County and City Health Officials (NACCHO) and the nearly 3,000 local health departments across the country, I write today to thank the committee for holding the hearing, on “E-Cigarettes: An Emerging Threat to Public Health.” NACCHO represents our nation’s county, city, metropolitan, district, and tribal health departments that are on the front lines of addressing tobacco use—including vaping and e-cigarette—each day.

Any tobacco product use, including e-cigarettes and other nicotine products, is unsafe, especially for youth. However, youth trends in tobacco use are going in the wrong direction. The Centers for Disease Control and Prevention has reported that in 2018 more than 1 in 4 (27%) high school students and more than 1 in 20 (7.2%) middle school students reported using an e-cigarette in the last 30 days¹. Even more concerning, among current tobacco product users, about 2 in 5 (1.68 million) high school students and 1 in 3 (270,000) middle school students used two or more tobacco products in 2018¹. E-cigarettes were the most commonly reported product used in combination with other tobacco products among both middle and high school students. While we are seeing trends of e-cigarette use skyrocketing among youth, the Journal of the American Medical Association reported e-cigarette use in adults, the intended users of the products, has remained stable and even showed signs of decline in use².

Local health departments are key partners with the healthcare system and non-governmental organizations to protect the health and well-being of their community and are instrumental in ensuring public awareness about the dangers of tobacco use, including e-cigarettes, particularly among youth. For example, NACCHO’s recently released report, *Tobacco Control Efforts in Rural America: Perspectives from Local Health Departments*, found that nearly all respondents (90%) reported engaging in tobacco and cessation activities and initiatives in the community, including education, referrals to Quitlines, social marketing campaigns, and cessation support groups. This same study highlighted the particular challenge of e-cigarette use to their regions, with 93% of respondents noting that e-cigarettes were a threat in their communities. These numbers reinforce what we are hearing from health departments of all sizes across the country: youth e-cigarette use is a big problem getting bigger. Local health departments are tackling this issue through both programmatic and policy channels by raising awareness and disseminating educational materials, providing support to parents and schools, ensuring local policies support tobacco-free kids, and continuing to promote evidence-based approaches to combat use among youth.



NACCHO

National Association of County & City Health Officials

The National Connection for Local Public Health

While addressing the increases in youth e-cigarette use, public health departments are also currently working to address an outbreak of lung illnesses related to vaping that has hospitalized 1,299 people and caused at least 26 deaths. While the causes of these illnesses are still under investigation, local health departments are working with their state and federal counterparts to raise awareness of the potential dangers of e-cigarette use, educate local health care providers about the warning signs, and track down evidence to help identify the root cause(s) of the outbreak. While these illnesses are not exclusive to the youth population, it is important to note that more than half of those cases identified have been in people under the age of 25, with 16% of cases being found in minors under the age of 18.

The alarming rise in e-cigarette use among youth calls for immediate federal action. Reports show that flavorings in e-cigarettes are a main contributor to the rise and appeal of vaping in our youth. That is one reason why NACCHO supports FDA's plan to ban flavored e-cigarettes and why we urge the Agency to formalize the policy as soon as possible. Moreover, more education is needed at the local level to inform parents and children about the dangers of nicotine on the developing brain and damage caused to the lungs by inhalation of dangerous, highly addictive substances. We also need to ensure that there are programs and services available to help youth who are addicted to these products to quit—something that is receiving far too little public attention. And we call on Congress to do all it can to reduce the availability, appeal, and use of e-cigarettes among youth to protect them from the dangers of nicotine and vaping by supporting efforts to remove enticing flavored e-cigarettes from the marketplace immediately.

Thank you for your leadership on this issue. For more information, please contact Adriane Casalotti, NACCHO's Chief of Government and Public Affairs, at acasalotti@naccho.org.

Sincerely,



Lori Tremmel Freeman, MBA
Chief Executive Officer

ⁱ Gentzke AS, Creamer M, Cullen KA, et al. *Vital Signs: Tobacco Product Use Among Middle and High School Students — United States, 2011–2018*. MMWR Morb Mortal Wkly Rep 2019;68:157–164. February 2019. DOI: <http://dx.doi.org/10.15585/mmwr.mm6806e1>.

ⁱⁱ *ibid*.

ⁱⁱⁱ Dai H, Leventhal AM. Prevalence of e-Cigarette Use Among Adults in the United States, 2014–2018. *JAMA*. Published online September 16, 2019. doi:10.1001/jama.2019.15331.



Ms. DELAURO. There are so many pieces here. You talked about devices. Well, part of the devices, some of those devices come from China. We haven't got a clue as to what they are, whether they explode, whether they don't, what are the repercussions of the devices themselves?

We have heard about the UK, and there is—there is really, in essence, a discussion about that data there, but you all have highlighted what is different here than what is different there. But the data is subject to whether it is criticism or whether it is real or not, et cetera.

So there is so many pieces that need to be investigated. We have an outbreak. We have epidemic levels. CDC will continue to investigate. I want them to be more clear in their recommendation. They are clear. But they recommend, they do not create the policy.

The FDA—and that is not in the jurisdiction here—but in the jurisdiction of the Agriculture Subcommittee, and the reason why I speak about that so because I sit on the Agriculture Subcommittee, and I am the senior member of that subcommittee. The FDA has got to uphold its mission.

We need to move faster. We need to take action. It is now a month since the Secretary said we were going to move forward on the flavors. Nothing has happened as of yet.

So, and you know, for decades the tobacco industry has lied to us. There are those of us who are sitting here will remember the hearing that Congressman Waxman had when each Member held their hand up and said that nicotine was not addictive. We don't put people in this committee under oath. Those folks were under oath at that time, and we found out that they were peddling false information.

And now we are looking at false information about e-cigarettes. It is not allowable for the tobacco industry to regulate itself. And if we so allow that, then we are not doing our job.

If we focus only on—we do have to focus on THC, but if we only focus there, we are missing the full scope of this effort. We need to provide more resources, which is what this subcommittee did, and we will go to battle with our colleagues on the Senate side so that we can provide the kinds of resources that are necessary for smoking and smoking cessation, but in addition, to building a public health infrastructure that can allow our very committed commissioners of public health around the country to be able to do their job, and so much of this responsibility is placed on the States.

So, again, I want to thank you. I want to thank my colleague, the ranking member, thank you. I know you had things to do as well, but thank you for being here.

Congressman Harris, thank you for hanging in it to the end.

But to all of you, let us keep on. Please make your voices heard. Thank you very, very much.

And let me conclude this hearing. Thank you.

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