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THE FISCAL YEAR 2022 HHS BUDGET

VIRTUAL HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTEENTH CONGRESS

FIRST SESSION

MAY 12, 2021

Serial No. 117–30

Published for the use of the Committee on Energy and Commerce
govinfo.gov/committee/house-energy
energycommerce.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE
48–145 PDF WASHINGTON : 2023

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C O N T E N T S

Page

Hon. Anna G. Eshoo, a Representative in Congress from the State of California, opening statement 2
Prepared statement 3
Hon. Brett Guthrie, a Representative in Congress from the Commonwealth of Kentucky, opening statement 4
Prepared statement 6
Hon. Frank Pallone, Jr., a Representative in Congress from the State of New Jersey, opening statement 7
Prepared statement 8
Hon. Cathy McMorris Rodgers, a Representative in Congress from the State of Washington, opening statement 9
Prepared statement 11

WITNESSES

Xavier Becerra, Secretary, Department of Health and Human Services 13
Prepared statement 15
Answers to submitted questions [1]

SUBMITTED MATERIAL

Letter of May 11, 2021, from Hon. Val B. Demings, et al., to Xavier Becerra, Secretary, Department of Health and Human Services, submitted by Mr. Tonko 83
Fact sheet, "Losing Texas' Waiver Extension Destabilizes the Health Care Safety Net," Texas Hospital Association, submitted by Mr. Burgess 88
Press release of April 19, 2021, Texas Council of Community Centers, Texas Council of Community Centers Expresses Deep Concerns About Impact of Federal Government's Reversal of the 10-Year 1115 Waiver Extension, submitted by Mr. Burgess 90
Article of April 30, 2021, "White House is split over how to vaccinate the world," by Dan Diamond and Jeff Stein, Washington Post, submitted by Mr. Burgess 91
Editorial of May 3, 2021, "A patent-free 'people's vaccine' is not the best way to help poor countries," Washington Post, submitted by Mr. Burgess 96
Letter of May 3, 2021, from Michelle McMurry-Heath, President and Chief Executive Officer, Biotechnology Innovation Organization, to President Biden, submitted by Mr. Burgess 98
Statement of Americans for Tax Reform, "Biden Admin Surrenders on American IP Rights," submitted by Mr. Burgess 101
Editorial of May 6, 2021, "Biden's Vaccine IP Debacle," Wall Street Journal, submitted by Mr. Burgess 103
Commentary of May 6, 2021, "President Joe Sanders," by Kimberley A. Strassel, Wall Street Journal, submitted by Mr. Burgess 107
Statement of AUTM, "Patent Waiver Strikes Damaging Blow to the Future of Innovation," by Stephen J. Susalka, Chief Executive Officer, submitted by Mr. Burgess 111
Statement of Novavax, May 7, 2021, submitted by Mr. Burgess 113

[1] Mr. Becerra's answers to submitted questions have been retained in committee files and are available at https://docs.house.gov/meetings/IF/IF14/20210512/112595/HHRG-117-IF14-Wstate-BecerraX-20210512-SD004.pdf.

Page

Letter of April 27, 2021, from Mr. Burgess, et al., to Xavier Becerra, Secretary, Department of Health and Human Services, submitted by Mr. Burgess 114
Letter of February 26, 2021, from Hon. Abigail D. Spanberger, et al., to Acting Secretary Cochran, Department of Health and Human Services, submitted by Mr. Burgess 118
Statement of Americans for Limited Government, "Biden's monumental World Trade Organization Covid mistake," May 10, 2021, submitted by Mr. Burgess 127
Statement of the Children's Hospital Association, "Impact of the Texas 1115 Waiver Extension Recission on Children's Hospitals," submitted by Mr. Burgess 128
Commentary of May 9, 2021, "Patent Busting Won't Help Vaccinate the World Faster," by Luciana Borio and Scott Gottlieb, Wall Street Journal, submitted by Mr. Burgess 129
Article of May 7, 2021, "North Carolina city could be next to house unaccompanied migrant children," by Anna Giaritelli, Washington Examiner, submitted by Mr. Hudson 133
Article of May 10, 2021, "Valley family pleads with FDA for access to experimental drug for fatal children's disease," by Sonu Wasu, ABC 15 Arizona, submitted by Mrs. Lesko 134

THE FISCAL YEAR 2022 HHS BUDGET

WEDNESDAY, MAY 12, 2021

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:30 a.m., via Cisco Webex online video conferencing, Hon. Anna G. Eshoo (chairwoman of the subcommittee) presiding.

Members present: Representatives Eshoo, Butterfield, Matsui, Castor, Sarbanes, Welch, Schrader, Ruiz, Dingell, Kuster, Kelly, Barragán, Blunt Rochester, Craig, Schrier, Trahan, Fletcher, Pallone (ex officio), Guthrie (subcommittee ranking member), Upton, Burgess, Griffith, Bilirakis, Long, Bucshon, Mullin, Hudson, Carter, Dunn, Curtis, Crenshaw, Joyce, and Rodgers (ex officio).

Also present: Representatives Doyle, Schakowsky, McNerney, Tonko, Clarke, Rice, and Lesko.

Staff present: Joe Banez, Professional Staff Member; Shana Beavin, Professional Staff Member; Jacquelyn Bolen, Health Counsel; Jeffrey C. Carroll, Staff Director; Waverly Gordon, General Counsel; Jessica Grandberry, Staff Assistant; Tiffany Guarascio, Deputy Staff Director; Stephen Holland, Health Counsel; Saha Khaterzai, Professional Staff Member; Una Lee, Chief Health Counsel; Aisling McDonough, Policy Coordinator; Meghan Mullon, Policy Analyst; Juan Negrete, Junior Professional Staff Member; Kaitlyn Peel, Digital Director; Tim Robinson, Chief Counsel; Chloe Rodriguez, Clerk; Samantha Satchell, Professional Staff Member; Kimberlee Trzeciak, Chief Health Advisor; Rick Van Buren, Health Counsel; C.J. Young, Deputy Communications Director; Alec Aramanda, Minority Professional Staff Member, Health; Sarah Burke, Minority Deputy Staff Director; Grace Graham, Minority Chief Counsel, Health; Nate Hodson, Minority Staff Director; Peter Kielty, Minority General Counsel; Emily King, Minority Member Services Director; Clare Paoletta, Minority Policy Analyst, Health; Kristin Seum, Minority Counsel, Health; Kristen Shatynski, Minority Professional Staff Member, Health; Olivia Shields, Minority Communications Director; Everett Winnick, Minority Director of Information Technology.

Ms. ESHOO. So good morning, everyone. Welcome to the Subcommittee on Health, which will now come to order.

Due to COVID–19, today's hearing is being, obviously, held remotely. All Members and witnesses will be participating via video conferencing.

As part of our hearing, microphones will be set on mute to eliminate background noise, and Members and our witness, you will need to unmute your microphone each time you wish to speak.

Documents for the record should be sent to Meghan Mullon at the email address we provided to your staff. And all documents will be entered into the record at the conclusion of the hearing.

The Secretary, as I said, has a hard stop at 2:00 p.m. Eastern Standard Time. So, as I just mentioned a few moments ago, I will be—I will have to enforce the 5-minute clock to ensure there is enough time for all subcommittee members to ask questions.

I know that there are full committee members that are joining us today. I hope we have time for you to ask questions. We will do our best, but the subcommittee members will, obviously, come first.

So the Chair now recognizes herself for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Welcome, Secretary Becerra. You are so welcome here, and we wish you every success. As you succeed in leading HHS, the American people will succeed.

The Secretary and I are classmates. We came into the Congress at the same time.

And Mr. Secretary, you have inherited a position with enormous responsibilities, especially as our Nation recovers from COVID–19. I think you are already making progress. HHS and the Biden administration have administered over 200 million COVID–19 vaccine doses and are on track to vaccinate 70 percent of American adults by the Fourth of July. That would be a new kind of celebration of the birth of our country. New COVID–19 cases are at—thank God—at a 7-month low. We are seeing children safely going back to school, States reopening, and normalcy—some normalcy—returning.

The Biden administration has moved quickly to reverse the damage done to our healthcare system by the previous administration: enrolling over 1 million more Americans in the ACA health coverage and reversing the draconian cuts to in-person enrollment help; rescinding the approval of several States' unlawful Medicaid work requirements; ending the discriminatory public charge rule, which would have penalized people for legally using healthcare services such as Medicaid; returning the U.S. to the World Health Organization; protecting women's health by proposing regulations to end the title 9 gag rule as well as ending the global gag rule; and ending discrimination in healthcare based on gender identity or sexual orientation. These actions are in addition to quickly and responsibly distributing the billions of dollars in emergency public health funding provided through the American Rescue Plan.

President Biden's fiscal year 2022 budget request continues these achievements by helping American families rebuild from the COVID–19 crisis, healthier and safer than before. The budget request addresses the systemic failures revealed by the pandemic, by restoring and expanding public health capacity by providing the

CDC with its largest budget increase in 2 decades—in 20 years—supplying $1.6 billion for the Community Mental Health Services Block Grant, more than doubling our Nation's mental health funding. That is an issue, Mr. Secretary, that every member of this subcommittee has spoken to and worked on.

Investing $10.7 billion to end the opioid crisis after last year's tragic record-high number of overdose deaths: another bipartisan issue. And addressing our Nation's racial health disparities by increasing the Indian Health Service's budget by $2.2 billion; and making major investments at the CDC to reduce maternal mortality, especially for Black women.

Importantly, the President's request also provides $6.5 billion to launch the Advanced Research Projects Agency for Health, ARPA–H, which holds the promise for transformational advanced biomedical research.

I very much look forward to hearing more about this today, about what the administration envisions for this agency, but there is still so much more to do. I think there always is.

Our national security is at risk, because our dependence on foreign manufacturing for medical supplies and pharmaceuticals continues. We are unprepared for the avalanche of patients who will need care for chronic long COVID. We still don't have an effective or easy-to-access treatment for COVID–19. And our Nation continues to face stark and persistent racial disparities in health coverage, chronic disease, and mortality.

So we have a lot more work to do, Mr. Secretary. We look forward to working with you to develop a budget and policies to improve our Nation's health and well-being. And we thank you for being with us today.

[The prepared statement of Ms. Eshoo follows:]

PREPARED STATEMENT OF HON. ANNA G. ESHOO

Welcome Secretary Becerra. You are so welcome here and we wish you every success. As you succeed in leading HHS, the American people will succeed. The Secretary and I are classmates, we came into Congress at the same time. And Mr. Secretary, you've inherited a position with enormous responsibilities, especially as our Nation recovers from COVID–19.

You're already making progress. HHS and the Biden administration have administered over 200 million COVID–19 vaccine doses and are on track to vaccinate 70% of American adults by the Fourth of July. That would be a new kind of celebration of the birth of our country. New COVID–19 cases are at, thank God, a 7-month low. We're seeing children safely going back to school, States reopening, and some normalcy returning.

The Biden administration has moved quickly to reverse the damage done to our healthcare system by the previous administration by:

- Enrolling over 1 million more Americans in ACA health coverage and reversing the draconian cuts to in-person enrollment help.
- Rescinding the approval of several States' unlawful Medicaid work requirements.
- Ending the discriminatory public charge rule, which would have penalized people for legally using healthcare services such as Medicaid.
- Returning the U.S. to the World Health Organization.
- Protecting women's health by proposing regulations to end the Title X gag rule, as well as ending the global gag rule.
- And ending discrimination in healthcare based on gender identity or sexual orientation.

These actions are in addition to quickly and responsibly distributing the billions of dollars in emergency public health funding provided through the American Rescue Plan.

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• Restoring and expanding public health capacity by providing the CDC with its largest budget increase in 20 years,

• Supplying $1.6 billion for the Community Mental Health Services Block Grant, more than doubling our Nation's mental health funding,

• Investing $10.7 billion to end the opioid crisis after last year's tragic record high number of overdose deaths,

• And addressing our Nation's racial health disparities by increasing the Indian Health Service's budget by $2.2 billion and making major investments at the CDC to reduce maternal mortality, especially for Black women.

Importantly, the President's request also provides $6.5 billion to launch the Advanced Research Projects Agency for Health (ARPA–H), which holds the promise for transformational, advanced biomedical research. I look forward to hearing more today about what the administration envisions for this agency.

But there's still more to do. Our national security is at risk because of our dependence on foreign manufacturing for medical supplies and pharmaceuticals continues. We're unprepared for the avalanche of patients who will need care for chronic long COVID. We still do not have an effective or easy-to-access treatment for COVID–19. And our Nation continues to face stark and persistent racial disparities in health coverage, chronic disease, and mortality.

So, we have a lot more work to do. We look forward to working with you to develop a budget and policies to improve our Nation's health and wellbeing. Thank you for your testimony.

Ms. ESHOO. The Chair now recognizes the ranking member of our subcommittee, the gentleman Mr. Guthrie, for his 5 minutes for an opening statement.

OPENING STATEMENT OF HON. BRETT GUTHRIE, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. GUTHRIE. Thank you, Chair Eshoo, for having this important hearing.

And thank you, Secretary Becerra, for being here today as we examine the fiscal year 2022 Department of Health and Human Services budget.

I was alarmed to see the amount of spending that the administration believes we can afford after reviewing the Biden administration's "skinny budget." In total, the proposed budget is more than an 8 percent increase over the amount appropriated for fiscal year 2021. This increase will be on top of the nearly 4 trillion Congress has already allocated for the COVID–19 pandemic in the first 5 COVID–19 relief bills.

I supported these relief bills that were focused on providing needed COVID-related assistance for our country; $1.3 trillion of this funding has yet to be disbursed from relief packages. That doesn't include the 1.9 trillion recently authorized for President Biden's COVID–19 package, which only 9 percent goes towards fighting the virus.

The HHS budget proposal in front of us today grows HHS by almost a quarter, with 131.7 billion included in the 1.5 trillion fiscal year 2022 budget.

I agree we need to improve public health infrastructure and better prepare for future public health emergencies. However, as we work on these improvements, we also have the responsibility to be good stewards of taxpayer dollars. We have seen firsthand how

public-private partnerships such as Operation Warp Speed have allowed this country to get vaccinated and reopen months ahead of our peers around the world. I hope we can work across the aisle to fully evaluate the programs that need support, and allocate funds wisely.

There is no doubt that we must continue to increase funding for the National Institutes of Health. In fact, Republicans have worked with Democrats to increase funding for NIH each year over the past five years. As we look at the budgets of Federal agencies that help with COVID–19 response efforts, we need to assess any increase in the context of their performance. I specifically want to mention my strong concerns with certain areas of what we know of the proposed budget.

First, I am pro-life. I believe in protecting the unborn. I am very concerned with President Biden's comments on removing the Hyde Amendment. Hyde has been around since 1976, and agreed upon for both Republicans and Democrats for its inclusion in appropriation bills for years. I strongly disagree with removing this protection and allowing taxpayer dollars to fund abortion procedures.

Secondly, I would like to speak with the current crisis at our southern border. Last Congress I served as ranking member of the Oversight and Investigations Subcommittee. The subcommittee held hearings on the management, care, and treatment of unaccompanied children. At that time, U.S. Customs and Border Patrol was experiencing a record number of encounters with unaccompanied children. And as a result, the Office of Refugee Resettlement was experiencing a number—record numbers of referrals. Since President Biden has taken office, there has been a rush of migrants arriving at our southern border. CBP and ORR are experiencing even higher numbers than they did in 2019.

According to CBP data, starting in January of this year, the number of UCs and single minor land border encounters each month has been higher than the numbers were during those same months in previous years. As of May 2nd, 2021, there were over 22,000 unaccompanied children in ORR's care. As a result, ORR has had to open several temporary influx care facilities and emergency intake sites, but has yet to open one of the temporary influx facilities that the Trump administration kept in a "warm" status to quickly stand up for surges in UC referrals.

Further, there have been reports of thousands of migrant children being kept in overcrowded Border Patrol facilities for longer than 72 hours. I joined several of my colleagues on this committee to request information from the Biden administration on capacity issues, allegations of abuse, and COVID–19 protocols. While we received responses to some of the questions yesterday, we await answers on the rest. The Biden administration must get a better grasp on handling this crisis and the massive influx of UC referrals.

Secretary Becerra, I appreciate you being here today, and I appreciate our phone call yesterday. And I look forward to hearing your testimony and responses to important questions from my colleagues, and I yield back my time.

[The prepared statement of Mr. Guthrie follows:]

PREPARED STATEMENT OF HON. BRETT GUTHRIE

Thank you, Chair Eshoo for having this important hearing, and thank you Secretary Becerra for being here today as we examine the fiscal year 2022 Department of Health and Human Services (HHS) budget.

I was alarmed to see the amount of spending that the administration believes we can afford after reviewing the Biden administration's "skinny budget." In total, the proposed budget is a nearly 9-percent increase over the amount appropriated for 2020. This increase would be on top of the nearly $4 trillion Congress has already allocated for the COVID–19 pandemic in the first five COVID–19 relief bills. I supported these relief bills that were focused on providing needed COVID related assistance for our country. $1.3 trillion of this funding has yet to be disbursed from those relief packages. That doesn't include the $1.9 trillion recently authorized from President Biden's COVID–19 package, which only 9% ended up going towards stopping COVID–19. The HHS budget proposal in front of us today grows HHS by almost a quarter with $131.7 billion included in the $1.5 trillion fiscal year 2022 budget.

I agree we need to improve our public infrastructure and better prepare for future public health emergencies; however, as we work on these improvements, we also have the responsibility to be good stewards of taxpayer dollars.

We have seen firsthand how public-private partnerships such as Operation Warp Speed (OWS) have allowed this country to get vaccinated and reopen months ahead of our peers around the world. I hope we can work across the aisle to fully evaluate the programs that need support and allocate funding wisely.

There is no doubt that we must continue to increase funding for the National Institutes of Health. In fact, Republicans have worked with Democrats to increase funding for the NIH each year over the past five years. As we look at the budgets of Federal agencies that helped with COVID–19 response efforts, we need to assess any increases in the context of their performance.

I specifically want to mention my strong concerns with certain areas of what we know of the proposed budget. First, I am pro-life. I believe in protecting the unborn. I am very concerned with President Biden's comments on removing the Hyde Amendment. Hyde has been around since 1976 and agreed upon for both Republicans and Democrats for its inclusion in appropriations bills for years. I strongly disagree with removing this protection and allowing taxpayer dollars to fund abortion procedures.

Secondly, I would like to speak to the current crisis at our southern border. Last Congress when I served as Ranking Member of the Oversight and Investigations Subcommittee, the Subcommittee held hearings on the management, care, and treatment of unaccompanied children (UC). At that time, U.S. Customs and Border Protection (CBP) was experiencing a record number of encounters with UC, and as a result, the Office of Refugee Resettlement (ORR) was experiencing a record numbers of referrals.

Since President Biden has taken office, there has been a rush of migrants arriving at the southern border. CBP and ORR are experiencing even higher numbers than they did in 2019. According to CBP data, starting in January, the number of UC and single minor land border encounters each month has been higher than the numbers were during those same months in previous years.[1] As of May 2, 2021, there were over 22,000 UC in ORR's care.[2] As a result, ORR has had to open several temporary influx care facilities and emergency intake sites but has yet to open one of the temporary influx facilities that the Trump administration kept in "warm" status to quickly stand up for surges in UC referrals. Further, there have been reports of thousands of migrant children being kept in overcrowded Border Patrol facilities for longer than 72 hours. I joined several of my colleagues on this committee to request information from the Biden administration on capacity issues, allegations of abuse, and COVID–19 protocols. While we received responses to some of the questions yesterday, we await answers on the rest. The Biden administration must get a better grasp on handling this crisis and massive influx of UC referrals.

Secretary Becerra, I appreciate you being here today, and I look forward to hearing your testimony and responses to important questions from my colleagues.

Ms. ESHOO. The gentleman yields back. The Chair now recognizes the chairman of the full committee, Mr. Pallone, for his 5 minutes of—opening statement, I am sorry.

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[1] https://www.cbp.gov/newsroom/stats/southwest-land-border-encounters.
[2] https://www.hhs.gov/sites/default/files/uac-program-fact-sheet.pdf

Good to see you, Frank.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Chairwoman Eshoo. This is, obviously, a very important hearing, and it is really great to see our new Secretary, who is one of our colleagues and a former member of the Democratic leadership, Xavier Becerra.

Great to see you, Xavier.

At last year's hearing with the Trump administration, Democrats highlighted the implications of massive cuts that were being proposed to vital health programs, while simultaneously hearing Federal witnesses attest to the terrifying potential of the then-new virus known as COVID–19. The Biden administration's fiscal year '22 budget request is, comparatively, a breath of fresh air, and we can now bolster our Nation's public health agencies by acting on this request.

I heard Mr. Guthrie express concern about the increases, but I believe that, given the pandemic, I think these increases are absolutely necessary. Overall, the request includes 131.7 billion for HHS and its adjoining agencies, a 23.5 increase from the 2021-enacted level. This includes critical investments to improve our Nation's public health preparedness, such as 905 million for the Strategic National Stockpile and 8.7 billion for capacity improvements and public health threat detection and assistance at the Centers for Disease Control. If enacted, this would be the largest budgetary increase for CDC in nearly 20 years.

The request also includes funding for vital safety net programs and for addressing health inequities in COVID–19 and beyond. It increases funding for CDC's Social Determinants of Health Program, it aims to reduce maternal mortality and morbidity through strengthening Maternal Mortality Review Committees, and provides a funding increase to the Indian Health Service, very important to many of our Members on this committee. It also provides an 18 percent budget increase for the Title X Family Planning program, and this program has historically served over 4 million low-income people a year by providing critical screenings and health services.

Now, the Biden administration's budget request would also expand cross-agency research capabilities to combat life-threatening diseases. Through the National Institutes of Health, it would establish the Advanced Research Projects Agency–Health, or ARPA–H, a research agency that would initially focus on diseases such as cancer, diabetes, and Alzheimer's. I look forward to learning more about how the proposed agency's activities may build off NIH's existing research to find lifesaving cures. I know the President talked about this in his address, Mr. Secretary.

And lastly, the budget request also makes significant investments in improving mental health and combating the opioid epidemic. It would provide $1.6 billion to the Community Mental Health Services Block Grant and 10.7 billion to fight the opioid crisis, which has been exacerbated—as we know, we have had hearings on this, Madam Chair—by the COVID–19 pandemic.

Now, these investments are bold and necessary, but we can't stop there. The COVID–19 pandemic laid bare the impacts chronic underfunding of public health has had on our surveillance, preparedness, and response efforts. And it is my hope to work with the Biden administration to ensure rebuilding our public health infrastructure is a key component of any jobs and infrastructure plan.

And we also have to take action to lower the cost of prescription drugs—the President mentioned it in his address—by passing H.R. 3, the Elijah Cummings Lower Drug Costs Now Act. And we have to make permanent the enhanced premium tax credits that we enacted into law on a temporary basis in the American Rescue Plan.

The administration recently announced that nearly a million Americans signed up for health coverage during the Special Enrollment Period, and the enhanced subsidies are reducing monthly premiums by over 40 percent. Thank you again, Secretary Becerra, for really pushing that Special Enrollment Period. I know how important it is to you.

We also have to ensure that low-income Americans have access to quality, affordable coverage. And now is the time to finish the work we began over a decade ago with the Affordable Care Act.

Now, I just wanted to say this. I heard Mr. Guthrie mention ORR and the southern border and the unaccompanied children.

You know, I have to be critical, Mr. Guthrie, because you somehow suggested that, you know, that the Trump administration played a positive role in this. Maybe that is not what you meant, but it sounded that way. And I have to say, after having gone through 4 years with the Trump administration, which forcibly separated children from their families, caused terrible damage to not only the children, but to the ORR program itself, I cannot see anything positive that came out of that.

You know, during the time that they were in charge, the Republicans on this committee refused to even hold a single hearing to examine what was happening and hold the Trump administration accountable for their outrageous actions. So, you know, the Biden administration was left with this decimated system, but they are working hard to process those children humanely. And thanks to you, I know we are going to hold a hearing within the next month in our Oversight and Investigations Subcommittee, where the head of the ORR will testify, and we will examine how the ORR program is functioning. I like to be bipartisan, but I can't excuse the Trump behavior on this. And I think the Biden administration is doing their best to deal with was what was left in a terrible situation.

Thank you, Madam Chair.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

At last year's hearing with the Trump administration, Democrats highlighted the implications of massive cuts that were being proposed to vital health programs while, simultaneously, hearing Federal witnesses attest to the terrifying potential of the then-new virus known as COVID–19.

The Biden administration's fiscal year 2022 budget request is, comparatively, a breath of fresh air. We can now bolster our Nation's public health agencies by acting on this request.

Overall, the request includes $131.7 billion for HHS and its adjoining agencies, a 23.5 percent increase from the 2021 enacted level. This includes critical invest-

ments to improve our Nation's public health preparedness, such as $905 million for the Strategic National Stockpile and $8.7 billion for capacity improvements and public health threat detection and assistance at the Centers for Disease Control and Prevention (CDC). If enacted, this would be the largest budgetary increase for CDC in nearly 20 years.

The request also includes funding for vital safety net programs and for addressing health inequities in COVID–19 and beyond. It increases funding for CDC's Social Determinants of Health program, aims to reduce maternal mortality and morbidity through strengthening Maternal Mortality Review Committees, and provides a funding increase to the Indian Health Service. It also provides an 18 percent budget increase for the Title X Family Planning program. The program has historically served over 4 million low-income people a year by providing critical screenings and health services.

The administration's budget request would also expand cross-agency research capabilities to combat life-threatening diseases. Through the National Institutes of Health, it would establish the Advanced Research Projects Agency–Health, or ARPA–H, a research agency that would initially focus on diseases such as cancer, diabetes, and Alzheimer's. I look forward to learning more about how the proposed agency's activities may build off NIH's existing research to find lifesaving cures.

Lastly, the budget request also makes significant investments in improving mental health and combating the opioid epidemic. It would provide $1.6 billion to the Community Mental Health Services Block Grant and $10.7 billion to fight the opioid crisis, which has been exacerbated by the COVID–19 pandemic.

These investments are bold and necessary, but we must not stop there. The COVID–19 pandemic laid bare the impacts chronic underfunding of public health has had on our surveillance, preparedness, and response efforts. It is my hope to work with the Biden administration to ensure rebuilding our public health infrastructure is a key component of any jobs and infrastructure plan.

We must also take action to lower the cost of prescription drugs for the American people by passing H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act. And we must make permanent the enhanced premium tax credits that we enacted into law on a temporary basis in the American Rescue Plan.

The administration recently announced that nearly a million Americans signed up for health coverage during the Special Enrollment period and the enhanced subsidies are reducing monthly premiums by over 40 percent.

We must ensure that low-income Americans have access to quality, affordable coverage. Now is the time to finish the work we began over a decade ago with the Affordable Care Act by once and for all closing the coverage gap, and ensuring that people have access to the protections of Medicaid regardless of what State they live in. We should also make permanent the American Rescue Plan's option to allow State Medicaid programs to cover women for 12 months postpartum.

The Trump administration forcibly separated children from their families, causing terrible damage to not only the children, but the ORR program itself. Yet during their time in charge, Energy and Commerce Republicans refused to hold even a single hearing to examine what was happening and hold the Trump administration accountable for their outrageous actions.

The Biden administration was left with a decimated system, but is working to process these children humanely. Thanks to the leadership of Secretary Becerra, I will hold a hearing within the next month in our Oversight and Investigations Subcommittee where the head of ORR will testify and we will examine how the ORR program is functioning.

I look forward to hearing from the Secretary today, and to working on our shared priorities moving forward.

I yield back.

Ms. ESHOO. The gentleman yields back. The Chair now recognizes the ranking member of the full committee, Representative Cathy McMorris Rodgers, for her 5 minutes for an opening statement.

OPENING STATEMENT OF HON. CATHY MCMORRIS RODGERS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WASHINGTON

Mrs. RODGERS. Thank you, Madam Chair. Good morning, everyone.

Just very quickly on the border: Under the Trump administration there was action taken very quickly to get more money, to actually get the border under control, to get families back together, to get more judges in place so that we could secure our border, and also help those that were knocking on our door. And I believe that more—we need—this needs to be a priority now.

Unfortunately, the crisis at the border is being ignored by the current administration. And I know we are going to work on that some more. This committee has been at the forefront of this issue.

Today we have Secretary Becerra with us, and I wanted to join in saying congratulations, and I too served with Secretary Becerra in the House of Representatives.

And I look forward to working with you in this new position. Certainly, as Secretary of the Department of Health and Human Services, you are at the forefront of a critical time in our Nation's history, and as we turn the corner on the pandemic. And really, thanks to the historic innovation of the private sector and the Trump administration's Operation Warp Speed, we are delivering fast and effective and safe vaccines to millions of Americans. And it is something that we came together to accomplish, and it is an American success.

We hope that your leadership will provide clear and consistent evidence-based guidance as we reopen, including 100 percent of our schools, and bring optimism to America again.

Mr. Secretary, after a year of lockdowns, fear, isolation, too many in our communities are battling the depths of despair. Our communities are seeing record-high overdose deaths. Mental health emergencies have increased. We know the pandemic and top-down government decisions from lockdowns and school closures, unfortunately, have made it worse. It is going to take our Nation's best and brightest in local communities, doctors, the private sector to fix these problems and deliver a solution that families desperately need and want.

We have broken families, we have broken systems, and we must address it. Unfortunately, socialized medicine, a government-run healthcare system, is not the solution. It will only lead to—it won't lead to personalized care. We need personalized care for every individual, every person, to have a chance for a better quality of life.

I am concerned about so many that have continued to advocate for a single-payer system and socialized medicine, Medicare for all. Centralized government healthcare is full of empty promises. This is the reality. Rather than provide certainty, it kicks roughly 180 million people off their employment-based plans and significantly raises costs. Rather than modernize our healthcare system to empower patients to catch up to the 21st century, Medicare for all would take us—would take back the clock to an outdated, politically influenced government takeover of our healthcare system.

Just like Speaker Pelosi's drug price control scheme, single-payer will destroy innovation for new cures and breakthrough medical treatment. It will also limit access. CBO reported, "Public plan might not be as quick to meet patients' needs, such as covering new treatments." That is CBO.

My colleagues and I aren't going to accept the empty promises of socialized medicine. I will take freedom over empty promises for

free stuff any day of the week. There is too much at stake as we crush this pandemic. Fight the depths of despair, and build a new future for a modern healthcare system. We should be taking action to make sure that people can make the best decisions for themselves.

And I did want to address the border crisis. Illegal border crossings remain at a 20-year high. More than 22,000 children are in facilities right now. This is a record. We need to hear what we are going to do to slow this down. And in many cases, the administration, unfortunately, has been silent. We need accountability. We need to have answers.

I appreciate you being here today. From the immediate crisis at the border to the long-term crisis that will result if we don't modernize our healthcare system, bring price transparency, empower individuals, empower patients, that needs to be our goal. So thank you again for joining us. I hope this is an opportunity to work together, to build trust, and to really focus on the American people and the best healthcare system in the world.

And with that, I yield back.

[The prepared statement of Mrs. Rodgers follows:]

PREPARED STATEMENT OF HON. CATHY MCMORRIS RODGERS

INTRO

Secretary Becerra, welcome to Energy and Commerce for the first time-and certainly not your last.

You are leading the Department of Health and Human Services through a critical time as America turns the corner of this pandemic...

... thanks to the historic innovation of the private sector and the Trump administration's Operation Warp Speed to deliver safe and effective vaccines.

Now the buck stops with you to provide clear and consistent evidence-based guidance as we reopen—including 100 percent of our schools—and bring optimism to America again.

HEALTHCARE CRISES TODAY

Mr. Secretary, after a year of lockdowns, fear, and isolation... our communities are battling the deaths of despair.

Communities are seeing record high overdose deaths.

Mental health emergencies have increased.

We know the pandemic—and top-down government decisions from lockdowns and school closures—made them worse.

It's going to take our Nation's best and brightest in local communities, doctors, and the private sector... to fix these problems and deliver the healthcare solutions families desperately need and want.

Decisions made by the Federal Government or by politicians won't solve broken families and broken systems.

It certainly won't lead to **personalized** care for every person to have a chance at a better quality of life.

Which brings me to your lifelong advocacy for a single payer system and socialized medicine.

EMPTY PROMISES OF MFA

Medicare For All—centralized government-run healthcare—is full of empty promises.

This is the reality:

Rather than provide certainty, it kicks roughly 180 million people off their employment based plans and raises costs.

Rather than modernize our healthcare system to empower patients to catch up to the 21st Century, Medicare For All would turn back the clock to an outdated, politically influenced, complete government takeover of our healthcare system.

Just like Speaker Pelosi's drug price control scheme... single-payer will destroy innovation for new cures and breakthrough medical treatments.

It will also limit access. CBO reported a "public plan might not be as quick to meet patients' needs, such as covering new treatments."

My colleagues and I aren't going to accept the empty promises of socialized medicine.

I'll take freedom over empty promises for free stuff any day of the week.

There's too much at stake as we crush this pandemic...

... fight the deaths of despair...

... and build the new future for a modern healthcare system.

We should be taking action to make sure people can make the best decisions for themselves to find the best care possible.

Now, is the time. It's what people deserve after this pandemic. It's what they deserve 10... 20... 30... years from now too.

That's why Republicans are leading for more price transparency—foundational to restoring the doctor-patient relationship.

... Lowering prescription drugs costs without government price controls that discriminate against Americans with disabilities and diseases.

... And spurring more private investment for breakthrough cures and treatments.

These are the priorities that will lead to a better healthcare future and improve people's quality of life for decades to come.

Before you release the full HHS budget...

...we urge you to take that into consideration and put aside any radical agenda that makes a lot of promises but falls short on real results.

BORDER

Now, turning to President Biden's border crisis.

Illegal border crossings remain at a 20 year high.

More than 22,000 children are in facilities under the care of Health and Human Services.

This is a record.

We need to hear from you an explanation on why the administration has been slow to address—**and in many cases has been silent**—on the ongoing public health and humanitarian crisis at the border.

We need accountability—not more blame shifting between administration officials.

We received your response yesterday to our request for information related to the management, care, and treatment of unaccompanied children.

Thank you but many questions remain unanswered and we expect HHS—under your leadership—to be more responsive to Congressional oversight.

We look forward to your response today.

CONCLUSION

From the immediate crisis at the border...

... to the long-term crisis that will result if we don't modernize our healthcare system...

... you have a lot of responsibility as Secretary.

I want to thank you again for joining us. I hope this is an opportunity to build trust and develop a strong working relationship.

Thank you.

Ms. ESHOO. The gentlewoman yields back. I now would like to introduce our witness. In so many ways he doesn't need an introduction, because so many of us know him well.

But let me just say that Secretary Becerra is the 25th Secretary of the Department of Health and Human Services. He previously served, just before he came back to DC, as the Secretary—served as the attorney general of the State of California, the second-largest Department of Justice in the country, outside of the DoJ in the—in Washington, DC. And he served, very importantly, for 12 terms in the United States House of Representatives. And we are all very proud of him.

We are very proud of you, Mr. Secretary. So welcome to the subcommittee. You are no stranger, obviously, to the House. While you were not a member of the Energy and Commerce Committee, you were a part of the tax writing. So you did the tax work, we did the big policies. And it is really great to see you. As I said, to the extent that you succeed in leading this agency, the Nation will succeed, so we want to work with you to ensure that.

So you are now recognized for your 5 minutes of opening statement. You look great, and take it away.

STATEMENT OF HON. XAVIER BECERRA, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. BECERRA. Chairwoman Eshoo, Ranking Member Guthrie, and members of the committee, first, great to see so many familiar faces, and thank you for the opportunity to appear before you to discuss the President's 2022 discretionary HHS budget.

The COVID–19 pandemic has shed light on how health disparities and the lack of national coordination and funding can leave us vulnerable to crises. Now, more than ever, we must assure that HHS has the resources to achieve its mission and protect the health of our communities. The budget President Biden has put forward is targeted and forward-thinking to meet Department goals.

For HHS the budget proposes $131 billion in discretionary budget authority. This $25 billion increase from fiscal year 2021 underscores the administration's commitment to prepare the Nation for the next public health crisis, to address disparities in healthcare, and to support our State and local partners, and as well to invest meaningfully in behavioral health, among other very important priorities.

To start, the budget provides $905 million for the Strategic National Stockpile, which has served a critical role in the COVID–19 response but is in need of upgrade.

The budget also makes the largest investment in CDC in almost two decades. With these 2022 investments, CDC will address preparedness within the United States and strengthen global health security. As we continue to confront new and emerging COVID–19 variants as well as an accelerating surge of cases in places like India, support for CDC's work is ever more important.

Madam Chair, the budget provides funding increases to address violence in our communities: $489 million to support and protect domestic violence survivors and $66 million to support victims of human trafficking and torture.

Gun violence, very much a public health issue, is addressed by doubling both CDC and NIH funding for firearm violence prevention research.

And to ensure that HHS is equitably serving all Americans, the discretionary request to invest over $200 million to reduce maternal mortality and morbidity, which disproportionately affects women of color, it funds a range of rural healthcare programs, and expands the pipeline of rural healthcare providers. It includes a $2.2 billion increase and advances appropriations for the Indian Health Services.

The budget increases funding for title 10 family planning programs to improve access to vital reproductive and preventative health services and to advance gender equity.

To help build the best possible future for our children, the budget provides $19.8 billion for the Department's early care and education programs, including 11.9 billion for Head Start, and 7.4 billion for the Child Care and Development Block Grant.

The budget also invests in improving the child welfare system, particularly to address racial inequity.

The President's budget also takes action to address the epidemic of opioids and other substance use, investing $10.7 billion across HHS and increasing access to medications for opioid use disorder and expanding the behavioral health provider workforce, particularly in underserved areas.

And in a notable investment, the budget provides $1.6 billion to the Community Mental Health Services Block Grant to respond to the systemic strain on our country's mental healthcare system.

To support innovation and research, the budget increases funding for NIH by $9 billion, 6.5 billion of which will go to establish the Advanced Research Projects Agency for Health, ARPA–H, with an initial focus on cancer and other deadly diseases. This major investment in Federal research and development will speed transformational innovation in health research and speed application and implementation of health breakthroughs.

HHS plays a critical role in promoting the well-being of those who come across our border seeking refuge. The budget reflects that commitment by increasing funding for the Office of Refugee Resettlement to rebuild the resettlement infrastructure and ensure unaccompanied children are safely cared for.

Finally, given the magnitude of HHS's work and the taxpayer dollars that are used to fund it, it is critical that we ensure our funds are used appropriately. The discretionary request invests in meaningful oversight and accountability, including efforts to combat fraud, waste, and abuse in Medicare, Medicaid, and private insurance.

I want to thank the committee for inviting me to discuss the President's fiscal year 2022 HHS budget, and I want to thank the staff at HHS for their Herculean effort in fighting COVID–19 and protecting the health of their fellow Americans.

To build back a prosperous America, we need a healthy America. President Biden's discretionary request builds on that vision.

Madam Chair, thank you.

[The prepared statement of Mr. Becerra follows:]

TESTIMONY OF SECRETARY BECERRA
BEFORE THE COMMITTEE ON ENERGY AND COMMERCE
MAY 12, 2021

Chairwoman Eshoo, Ranking Member Guthrie, and Members of the Committee, thank you for the opportunity to discuss the President's fiscal year (FY) 2022 discretionary budget request for the Department of Health and Human Services (HHS). I am pleased to appear before you for the first time as Secretary to discuss the President's discretionary request, and I look forward to continuing to work with you.

HHS is at the center of many challenges facing our country today—the COVID-19 pandemic, safely caring for unaccompanied children, the opioid and substance use crisis, gun violence, racial inequality, and more—and we are rising to meet those challenges. I am honored to be given the responsibility to lead HHS at this time.

COVID-19 has shed light on how health inequities and insufficient Federal funding can leave communities vulnerable to crises. The President's discretionary request invests in America, demonstrates a conscious effort to address racial disparities in health care, tackles the opioid crisis, and puts us on a better footing to take on the next public health crisis.

Now more than ever, we must ensure HHS has the resources to achieve its mission and tackle these challenges after years of underfunding. The President has put forward a discretionary request that does just that. The FY 2022 discretionary request proposes $131.7 billion in discretionary budget authority for HHS, an increase of $25 billion from FY 2021 appropriations. The Labor-HHS total is $119.5 billion, an increase of $23 billion. This discretionary request underscores the Administration's commitment to serve families across the country, with investments in priority areas such as behavioral health (mental health and substance use), maternal health, emerging health threats, science, data and research, tribal health, early child care and learning, and child welfare.

To build back a prosperous America, we need a healthy America, and President Biden's discretionary request builds on that vision.

Preparing for the Next Public Health Crisis

The fight against COVID-19 is not yet over. Even as HHS works to beat this pandemic, we are also preparing for the next public health crisis. The FY 2022 request makes significant investments in our preparedness and response capabilities.

The Strategic National Stockpile, within the HHS Office of the Assistant Secretary for Preparedness and Response, has served a critical role in the COVID-19 response, deploying personal protective equipment, ventilators, and medical supplies to states, cities, and territories across the country. The discretionary request provides $905 million for the stockpile, $200

million above FY 2021, to ensure the stockpile is ready to respond to future pandemic events and any other public health threats, including maintaining a robust inventory of critical medical supplies and modernizing the stockpile's distribution model. The discretionary request also supports a strong public health workforce, and addresses gaps in the existing public health infrastructure, including at the state and local levels.

During this pandemic, we have seen the critical role of the Centers for Disease Control and Prevention (CDC). To ensure that CDC is well positioned to address current and emerging public health threats, the discretionary request restores capacity to the world's preeminent public health agency, by investing an additional $1.6 billion over the FY 2021 level for a total of $8.7 billion. This is the largest budget authority increase for CDC in almost two decades. A core function of CDC is partnering with state, tribal, local, and territorial entities, and this funding will enhance that partnership. The discretionary request will also provide CDC with additional resources to further develop and expand teams of highly trained and deployable public health experts to support preparedness at the local level.

The COVID-19 pandemic has also shown the importance of producing reliable data. Bad inputs lead to bad outputs, and without good data, the CDC cannot effectively prepare for, or respond to, public health threats and make well-informed decisions to protect the American people. With funding provided in the FY 2022 discretionary request, the CDC will build upon investments in the data infrastructure to date and continue efforts to modernize public health data collection and analysis nationwide.

Public health threats know no borders, and CDC is working to prevent, detect, and respond to emerging global biological threats at home and abroad. As we continue to confront new and emerging COVID-19 variants, as well as an accelerating surge of cases in India, support for CDC's work is even more important. With the President's proposed FY 2022 investments, CDC will not only address preparedness within the United States, but also support core public health capacity improvements overseas and strengthen global health security by improving its ability to deploy experts internationally, and support efforts to prevent, detect, and respond to emerging global biological threats. CDC will invest in global health security and continue to fight health threats worldwide while simultaneously enhancing domestic preparedness to address threats here at home. Domestic health is increasingly impacted by global factors and the CDC's global health security efforts include conducting research to ensure efficient disease response.

While we prepare for future pandemic threats, we are also facing a public health crisis that is already here: violence in our communities. The current public health emergency has shone a light on the issue of domestic and gender-based violence. More than 1 in 4 women and more than 1 in 10 men have experienced contact sexual violence, physical violence, or stalking by an intimate partner and reported significant impacts. The discretionary request provides $489 million for the Administration for Children and Families (ACF) to support and protect domestic violence survivors, which is more than double the FY 2021 enacted levels. The budget

also provides $66 million for victims of human trafficking and survivors of torture, more than 45 percent above FY 2021 enacted levels.

We have also seen the devastating impact of gun violence in communities across the country. Almost 40,000 people die as a result of firearm injuries in the United States every year, while homicide is the third leading cause of death for people ages 10-24. This is a public health issue, and one that disproportionately impacts communities of color. The budget addresses this crisis by doubling CDC and the National Institutes of Health's (NIH) funding for firearm violence prevention research. The discretionary request also provides $100 million to CDC to start a new Community-Based Violence Intervention initiative, in collaboration with the Department of Justice, to implement evidence-based community violence interventions at the local level.

Caring for all Americans Through Health and Human Services

Central to the HHS mission is the charge to enhance the health and well-being of all Americans. The discretionary request invests in areas across HHS to ensure we are equitably serving the American people. As Secretary, I will ensure this focus is fundamental to all of our work.

The United States has the highest maternal mortality rate among developed nations, with an unacceptably high mortality rate for Black and American Indian/Alaskan Native women. Addressing this critical public health issue is a major priority of this Administration. Building on HHS's longstanding efforts to improve maternal health, the discretionary request provides more than $200 million to reduce maternal mortality and morbidity by implementing evidence-based interventions to address critical gaps in maternity care service delivery and improve maternal health outcomes. This includes increased funding to CDC's Maternal Mortality Review Committees and the Health Resources and Services Administration's (HRSA) Rural Maternity and Obstetrics Management Strategies program. HRSA also prioritizes maternal health through its Title V Maternal and Child Health Block Grant and Alliance for Innovation on Maternal Health programs. As with all our public health work, collecting good data will be critical to this effort.

HRSA's work is central to our focus of serving all Americans given their mission to improve health outcomes and address health disparities. HRSA-funded Health Centers provide access to care for low-income and marginalized populations, and they serve 1 in 11 people in the nation. The discretionary request increase to workforce diversity programs highlights HRSA's commitment to supporting health care providers dedicated to working in underserved areas and building toward a workforce that reflects the communities they serve and is able to provide culturally relevant care. HRSA ensures equitable access to services and supports for low-income people with HIV through Health Centers as well as the Ryan White HIV/AIDS Program. In 2019, 88.1 percent of Ryan White HIV/AIDS Program clients were virally suppressed, a record level that exceeds the national average of 64.7 percent. HHS will continue efforts to end the HIV/AIDS epidemic in the United States by working closely with communities where HIV transmission occurs most frequently to implement effective prevention, diagnosis, and treatment

strategies, and will address the disproportionate impact of HIV and Hepatitis C infections in Tribal communities.

Also, directly connected to the HHS mission is the need to provide access to high-quality care, no matter where you live. HHS will continue to focus on the unique needs of rural communities. HHS has a range of programs that address rural health, from those with large service populations like Health Centers, to targeted populations like the Black Lung Clinics Program. The FY 2022 discretionary request promotes services to coal miners and their families through quality medical, outreach, educational, and benefits counseling services. It also provides funding to increase the number of individuals training in rural communities, as research has shown that providers are likely to remain in the communities where they train as residents.

HHS will also address the stark health disparities that persist in Tribal communities by investing in the Indian Health Service (IHS), which serves over 2.6 million American Indians and Alaska Natives. The COVID-19 pandemic's devastating impact on Tribal communities has demonstrated the real human toll of these disparities. The discretionary request provides a $2.2 billion, or 36 percent increase for IHS in order to take a historic step to address chronic underfunding and expand access to high-quality health care across Indian Country. It also proposes advance appropriations for IHS to provide stability for the Indian Health system and parity with how other Federal health agencies are funded. I am committed to strengthening the Nation-to-Nation relationship between the United States and Indian Tribes. To this end, the discretionary request supports self-determination through a consultative process to consider long-term solutions, including mandatory funding, to ensure adequate and stable funding for IHS.

The discretionary request also expands access to family planning health care services, providing an 18.7 percent increase to the Title X Family Planning program to improve access to vital reproductive and preventive health services, and to advance gender equity. In 2019 alone, Title X-funded clinics served more than 3.1 million family planning clients seen through 4.7 million encounters.

Investing in Children's Futures

Our experiences as children shape the adults we become, and support in childhood can mean success in the future. As Frederick Douglass wrote, "It is easier to build strong children than to repair broken men." HHS is committed to supporting vulnerable children to help build them the best possible future. The discretionary request provides $19.8 billion for the Department's early care and education programs in ACF, $2.8 billion over FY 2021 enacted. This includes $11.9 billion for Head Start, which helps young children enter kindergarten ready to learn. Head Start programs deliver services through 1,600 agencies in local communities, and they provide services to more than a million children and pregnant women every year, in every U.S. state and territory. In addition, the discretionary request provides $7.4 billion for the Child Care and Development Block Grant, $1.5 billion over FY 2021 enacted, to expand access to quality child care for families in all corners of the country. Over a million children receive child care

subsidies every month funded by the Child Care and Development Fund, and nearly half of the families receiving child care subsidies reported income below the Federal Poverty Level. These investments will improve outcomes for children across the country.

The discretionary request also invests in improvements to the child welfare system, particularly to address its racial inequity. The discretionary request provides $100 million in new competitive grants for states and localities to advance reforms that would reduce the overrepresentation of children and families of color in the child welfare system and address the disparate experiences and outcomes of these families. This funding will also give more families the support they need to remain safely together. The discretionary request also provides $200 million for states and community-based organizations to respond to, and prevent, child abuse, over 30 percent above FY 2021 enacted.

Combating Mental Health and Substance Use Crises

HHS must address the public health crises associated with mental health and substance use disorders. This need is especially urgent given that both crises have accelerated during the COVID-19 pandemic. Calls to mental health helplines have increased across the country as Americans struggle with increased anxiety, depression, risk of suicide, and trauma-related disorders resulting from the pandemic. Younger adults, racial minorities, essential workers, and unpaid adult caregivers are particularly impacted. Similarly, preliminary data from 2020 suggests that overdose deaths, which were already increasing, accelerated during the pandemic. Provisional data suggest that over 90,000 drug overdose deaths occurred in the United States in the 12 months ending in September 2020. That represents a year-over-year increase of close to 29 percent.[1]

The discretionary request addresses these crises through investments in the Substance Abuse and Mental Health Services Administration.

In a historic investment, the discretionary request provides $1.6 billion to the Community Mental Health Services Block Grant to respond to the systemic strain on our country's mental health care system—more than double the FY 2021 level. To address the undeniable connection between the criminal justice system and mental health, the discretionary request will also invest in programs for people involved in the criminal justice system. HHS will also focus on the behavioral impact of COVID-19, including on children. When children and young people face trauma, it can continue to affect them across their lifespan, so it is critical we intervene now to support their social, emotional, and mental well-being.

The discretionary request also takes action to address the epidemic of opioid and other substance use, investing $10.7 billion across HHS, $3.9 billion more than in FY 2021. The impact of this epidemic is felt in our communities, and the budget will direct funding to states and Tribes to

[1] Centers for Disease Control and Prevention. (2021). Vtial Statistics Rapid Release: Provisional Drug Overdose Death Counts. Retrieved May 6, 2021 at https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

increase community-level response. The discretionary request will also increase access to medications for opioid use disorder and expand the behavioral health provider workforce, particularly in underserved areas. I greatly appreciate the investments the American Rescue Plan provided to the Substance Abuse Prevention and Treatment Block Grant, Mental Health Block Grant, and Certified Community Behavioral Health Centers, and HHS will continue to build on these efforts. This crisis is also evolving—overdose deaths involving substances other than opioids are also increasing. HHS will ensure our work is responsive to the needs of communities across the country.

Promoting Biomedical Research

HHS work is responsible for major scientific breakthroughs, and we are committed to supporting innovative science and research in order to advance the health and well-being of our nation. As the world's premier biomedical research agency, NIH will continue to be at the forefront of scientific advancements. The discretionary request includes $51 billion for NIH, a $9 billion increase or 22 percent increase over FY 2021 enacted. Included in this increase is $6.5 billion to establish the Advanced Research Projects Agency for Health (ARPA-H). With an initial focus on cancer and other diseases such as diabetes and Alzheimer's, this major investment in Federal research and development will speed transformational innovation in health research and speed application and implementation of health breakthroughs.

This bold new approach will complement NIH's existing research portfolio, which is a vital contributor to longer and healthier lives, supports and trains world-class scientists, and drives economic growth. Outside of ARPA-H, the remaining $2.5 billion increase will allow NIH to continue investing in basic research and translating research into clinical practice to address the most urgent challenges such as HIV/AIDS and ending the opioid crisis. This also includes climate change, which the Administration is working to address government-wide. At NIH, the discretionary request includes an increase of $100 million to support research aimed at understanding the health impacts of climate change.

Restoring America's Promise to Refugees

HHS plays a critical role in promoting the wellbeing of those seeking refuge or relief in the U.S. The FY 2022 discretionary request provides over $4.4 billion to the Office of Refugee Resettlement (ORR) – an increase of over $2.5 billion above FY 2021 enacted. This funding would allow ORR to support the Presidential Determination to increase the refugee admissions ceiling to 62,500 refugees this fiscal year and to continue to rebuild the resettlement infrastructure in order to resettle up to 125,000 refugees in FY 2022.

This funding increase also reflects a commitment to ensuring unaccompanied children are provided with care and services that align with child welfare best practices while they are in ORR's custody, and unified with relatives and sponsors as safely and quickly as possible. Despite significant challenges posed by COVID-19 and policies from the previous administration, HHS is humanely caring for unaccompanied children while working to unify

them with a vetted sponsor. Working across government and in close partnership with the Department of Homeland Security, we have substantially increased our ability to quickly facilitate the transfer of children out of U.S. Customs and Border Patrol custody and into child-appropriate settings, including with fully vetted sponsors.

Funding Core Program Operations

It is simply not possible to meet the HHS mission and address all these key changes without sufficient funding to cover our operational needs. The FY 2022 discretionary request invests to bolster operations. It strengthens administrative and operational resources throughout the Department needed to ensure proper stewardship of resources entrusted to HHS by Congress.

Providing Oversight and Program Integrity

Given the magnitude of HHS's work—and the taxpayer dollars used to fund it—it is critical that we ensure our funds are used appropriately. The discretionary request invests in program integrity, including efforts to combat fraud, waste, and abuse in Medicare, Medicaid, and Private Insurance.

Conclusion

I want to thank the Committee again for inviting me to discuss the President's FY 2022 discretionary request for HHS. In the coming weeks, the Administration will release a budget that builds on this discretionary funding request and offers a comprehensive fiscal vision for the nation that reinvests in America's health, supports future growth and prosperity, and meets U.S. commitments in a fiscally sustainable way. I look forward to continuing to show how HHS helps fulfill that vision.

Ms. ESHOO. Thank you, Mr. Secretary. We will now move to Member questions, and the Chair recognizes herself for 5 minutes.

You mentioned ARPA–H, and I am glad that you did. The President's budget contains $6.5 billion in it to create this new independent agency. Tell me what you—what the rationale is to have this in NIH. This is modeled on DARPA and ARPA–E, and it doesn't seem to me that, as extraordinary as NIH is, and the work that they do, that, you know, that successful independence that is the imprimatur of DARPA and ARPA–E is really there. So that is my—I know that you support the subagency, but if you could, comment on where you think it needs to be.

Two other things. Our subcommittee was the first in the Congress to have a hearing on long COVID. We have powerful testimony, Mr. Secretary, from patients. When I asked both the CDC and NIH—because they both testified—when I asked them who is leading the coordinated whole-of-government response to what is taking place with long COVID, we were told there was no such leader or coordinator at HHS. So we need you to tell us, you know, what you are going to do about that. We need a coordinated response from the government, and we need someone to lead that.

On the $6 billion provided for HHS for therapeutics in the American Rescue Plan, I think that we need a strategy for supporting the development of an effective therapeutic. It has been over a year since we have been—the pandemic has visited us, and the current monoclonal antibody therapies on the market really have not been as successful as we would have hoped. But newer monoclonal antibodies are being developed that could be delivered outside of a hospital setting, which is really important, and I think could be effective against variants. So I would like you to tell us how you are going to spend that $6 billion.

And on the Provider Relief Fund, I think maybe someone mentioned that in their opening statement. I think that the Trump administration failed at managing this. The money went out too slowly, and it wasn't a transparent process. So can you clarify for the subcommittee how much money remains in the Provider Relief Fund, and when you plan to disperse it, and is there a priority order for who receives it next?

And my last question is I think that we need more resources in the FDA for inspections, both domestic and foreign. The foreign inspectors, actually, their work is voluntary. And I think that we have a long, long way to go on this. The American people depend on these inspections. Look what happened at Emergent. I mean, it is a national disgrace.

So those are all my questions, Mr. Secretary, and you have 2 minutes to answer. And if you can't answer all of them, of course, you will respond in writing. So welcome, and thank you.

Mr. BECERRA. Thank you. I was actually going to take 2 minutes to just say thanks for having me and great to be with you. So I will try to cut that out, and go right to the questions.

First, on ARPA–H, Madam Chair and Members, I think what President Biden is saying is we know what basic research can do for us. It leads to some of the greatest scientific discoveries. But sometimes we have got to move it faster because, for some people, contracting a disease is a death sentence, and it is a quick death

sentence. So what President Biden has simply said is, let's accelerate this. If we have something innovative, something promising in the works, let's jump on it.

And I applaud President Biden for wanting to devote energy—we can't do it with every particular condition or disease, but we can focus. You mentioned cancer. We talked about some of the deadly diseases. We can name any number of them. But what he is saying is we are going to partner with the private sector——

Ms. ESHOO. But where do you want to put it? What is your view as to where this should be?

Mr. BECERRA. Well, I certainly know that NIH continues to do the basic research. I think we have any number of places that we could feel comfortable with it. But NIH continues to do the basic research. If we want to just lift that up and launch faster, we can discuss that.

But the important thing is that we launch, and not let issues about—bureaucratically, where we are going to locate ARPA–H, get in the way of a great idea, because there are communities out there clamoring for us to help them find that next discovery that keeps their loved one alive.

Let me—should I move on to some of the other questions——

Ms. ESHOO. Please, as quickly as possible.

Mr. BECERRA. Sure. COVID response by HHS. Here I will tell you, Madam Chair, that we are fortunate to have the experts. We know this, whether it is CDC, at FDA, NIH. And with the President's team working on this, as well, at—we are coordinating. But there is—everyone is at the helm, all hands on deck. I can tell you that you don't put more than 200 million shots in arms in a little over 100 days if you are not coordinating and working together.

And so, at HHS, we have a team that will continue forward, working closely with the President. This is the priority, is making sure we beat out the COVID launching——

Ms. ESHOO. My time has expired, Mr. Secretary. Thank you again. It is great to see you. And the Chair now recognizes Mr. Guthrie, again, the ranking member of our subcommittee, for his 5 minutes of questions.

Mr. GUTHRIE. Thank you, Madam Chair, and thanks, Mr. Secretary, for being here. And we did have hearings on the border before, and ORR before us. As a matter of fact, when we had the professionals before us, they said that the position really changed at the border.

The situation got so much better after Congress finally passed the supplemental bill. And the supplemental was asked for some—I don't have the numbers in front of me, because I didn't prepare for this line of discussion, but the supplemental some time in midspring was asked for by the administration. We didn't pass it until some time in midsummer—I do not know that for a fact—with a majority of Republican votes. And the people who had the biggest concerns in the hearing voted against the supplemental. So I just want to set that record straight.

But we did have your predecessor before us, Mr. Secretary. And as a matter of fact, there were some very passionate discussions from colleagues on the other side of the aisle to the point, when he got up and left, I said, "Who in the world would want to take one

of these jobs?" And so I just want to say I am going to treat you with respect, and with—because your office deserves it, and you deserve it, as a person. So I appreciate that. But just because I am doing that doesn't mean I am less passionate about what is going on at the border today.

And I just want to talk about—there was a—there was an article, I guess it was in Texas, investigating abuse allegations at a migrant facility. Just—it is the migrant facility in San Antonio that is holding over 1,600 unaccompanied children, and the allegations of sexual abuse, insufficient staffing, children not eating, and tested positive for COVID not being separated. And I know you are aware of that.

I just wanted to say, has ORR investigated these allegations? And if so, what can ORR share about these allegations?

And have you had the opportunity to visit an ORR facility? I know I have had the opportunity to do so. And if not, when do you plan to do so?

So if—the allegations, and if they have been investigated, would be the first question.

Mr. BECERRA. Congressman Guthrie, thank you very much for the question, and thank you also for the manner in which you have asked the question. I appreciate that.

We are absolutely on top of any reports, any allegations of abuse. We take our role very seriously in making sure that, not only do we follow the law when it comes to the care of these migrant children, but that we provide them with the well-being that they deserve while they are in our custody. Temporary as it might be—and we don't get into the discussion about their immigration status, whether they are going to be sent back home or not—but we make sure we take care of them. So any report we will investigate, and we continue to do that.

But what I can tell you is the several thousand children that have come through our custody are all being cared for and cared for well.

Mr. GUTHRIE. Thank you. I think they were before, once they got into the ORR facility. You have some professionals there that are outstanding, and they really worked hard and did a really, really good job.

So switching to drug pricing, we are—all want lower drug pricing. All Americans want lower drug pricing. Though the President said in the State of the Union, as we talked about, that if we can't agree on everything, let's at least pass the things that we agree on. We have a bill, H.R. 19, that has 36, I think, unanimous, bipartisan bills that will make an effect on drug prices.

Some people say it is small ball. It is not. If you reform Medicare Part D, it is every American over 65.

And so what we want to talk—ask—the question is, one, can we not proceed on areas in which we agree, which would be H.R. 19, that does make a difference?

And if we go with H.R. 3, we had a hearing the other day, and the witness on the Democrat side kept talking about it would just be a—10 to a dozen bills, and bills that have been around—I mean, pills, or drugs that have been around for a long time and, there-

fore, really wouldn't affect innovation, because they have been around for a long time.

But we all know that, in any business, you take your previous revenues and put them into your research to move forward. So I do think that was very dismissive of the problem of—H.R. 3 could case in moving forward. So can we not work together on what we agreed on?

And two, if H.R. 3 is part of a package, it—let's hope it is not going to be a pay-for for other priorities. For instance, these are people's premiums, people's payroll taxes that they put in. We want to make sure that money—can you commit that money will stay in Medicare?

Mr. BECERRA. Well, Congressman, let me first agree with you, we need to work together. And I hope that you will test us at HHS if you need technical assistance, if our team can be of any service in helping you noodle through the particular issue, as we try to tackle what I think every American agrees with, and that is that we have to lower drug prices. Then, hopefully, we will—not only will the working together produce results, but we will do it quickly.

And so I can guarantee you that, if you give us an assignment, we will take it on. And if you give us dollars to make it happen, we will keep that money where it is supposed to stay. We will follow the law. Whatever you all decide to pass, we will implement it and make sure we comply with whatever the prescriptions are within that legislation that you pass and have become law

Mr. GUTHRIE. I only have 10 seconds. So would the administration, though, want the Medicare money to stay in Medicare if——

Mr. BECERRA. We want to make sure——

Mr. GUTHRIE. Yes.

Mr. BECERRA. We certainly want to make sure that we are improving Medicare. And so we will look at what you all send us to make sure that we can not only improve Medicare but make healthcare better for all Americans.

Mr. GUTHRIE. Thank you. Thank you for being here, and thank you for your testimony. And I yield back.

Ms. ESHOO. The gentleman yields back. The Chair is now pleased to recognize the chairman of the full committee, Mr. Pallone, for his 5 minutes of questions.

Mr. PALLONE. Thank you, Madam Chair. And again, I don't want to pick on Mr. Guthrie, but I don't think he accurately portrayed what happened at the H.R. 3 hearing or what happened at the border.

I mean, it is clear that President Trump's administration forcibly separated kids from their families at the border and caused terrible damage to the kids into the ORR program. You know, I don't want to debate that here, but I mean, to suggest otherwise I just don't think is accurate.

Also, it—the President said in his joint address that he wanted to have legislation passed this year to lower the price of prescription drugs by giving his administration the power to negotiate prices, and specifically said that that money should be a pay-for for healthcare programs. I mean, I don't think there is any question that that should be used for, you know, things like ACA, Medicare,

Medicaid. That is the President's position, and that is certainly my position.

But I wanted to get into—quickly, if I could, Mr. Secretary, ask about negotiated prices, about public health infrastructure, and then, finally, mention the Provider Relief Fund. So let me quickly get into this.

On the prescription drug issue in H.R. 3, I just want your opinion. The testimony at the hearing last week is that, in order to effectively reduce prescription drug costs, we have to have a comprehensive solution like H.R. 3 that includes negotiated prices. And so, from your perspective, is empowering the Secretary to negotiate drug prices an essential tool to lowering drug prices?

Mr. BECERRA. Chairman, absolutely. I think the President has made that very clear, and I will restate that. Absolutely, if we want to lower those drug prices, we have to have the ability to negotiate.

Mr. PALLONE. Well, thank you. Now, let me get to this second thing.

In both the LIFT Act, which is our committee's infrastructure piece, and the Moving Forward Act, which passed in the House in the last session, we specifically included protecting and investing in the public health infrastructure. And I am not asking you to specifically comment on that legislation, but I just wanted to know whether you would support investments for our public health infrastructure—for example, improving our public health labs' infrastructure or modernizing our hospital infrastructure. We would like to have that as a component of any infrastructure package considered in Congress.

And I know you said that you would support whatever we put forward, and that is fine. But I want you to—I wanted you, if you would, to comment on the need to have a public health infrastructure component in this, if you would.

Mr. BECERRA. Mr. Chairman, there is no doubt that the President and we at HHS have a wish list of what we would love to see you do, but we ultimately will work with whatever you are able to pass.

But without a doubt, we must end the cycle of boom and bust funding for our public health infrastructure. We have to make the kinds of investments that we saw in the American Rescue Plan. That helped to secure long-term funding at the Federal, State, and at the local level. And so, for sure, we have to do this the right way, that gives real certainty moving forward of how we are going to be able to expand healthcare and make it more affordable.

Mr. PALLONE. All right. And the last thing, I guess, is not really a question, Xavier, but I did want to mention it. I wanted to mention that I am very interested in how the Department is distributing the critical funds provided by Congress over the last year through the Provider Relief Fund.

You know, I was constantly trying to push your predecessor to get this money out in an effective way during the COVID crisis. And I understand our staffs have been in touch to schedule a briefing on the funds that remain. And I just want to urge the administration to permit providers who have received these critical funds to extend their availability through the end of 2021, as we continue to respond to COVID.

You know, this Provider Relief Fund ensures that frontline workers can keep their doors open during this time, and it is just imperative that the funds go to those who need it the most.

Again, I am not asking you a question, but you know—and everybody on this committee on both sides of the aisle knows—that we were very concerned during the pandemic under the Trump administration with the various tranches that some of that—much of it was not using formulas that actually got it out to the areas that had the greatest need. And so I just want to express our concern. If you want to comment on it, you can. I am not asking you a question, but if you want to comment on it, you certainly can.

Mr. BECERRA. Mr. Chairman, we hear you loud and clear. We couldn't agree more with what you have just said.

And I will only add that, for me, what will be important with regard to the Provider Relief Fund, having been at the State level at the time that it was first being implemented, we are going to demand accountability and transparency as we disburse the remaining 25 billion or so that was originally in the pot and also the 8 billion or so that was made available for our rural communities.

Mr. PALLONE. Thank you so much.

Thank you, Madam Chair.

Ms. ESHOO. The gentleman yields back.

The Chair now recognizes the ranking member of the full committee, Mrs. McMorris Rodgers, for your 5 minutes of questions.

Mrs. RODGERS. Thank you, Madam Chair. I am concerned. I am concerned, because it sounds like the Democrats want to take the Medicare dollars and pay for ACA policy again. But I am going to move on.

Mr. Secretary, I thank you for your commitment to price transparency. You recently responded to a letter, and I do hope that that is an area where we can work together to enforce the rule and continue to get that price transparency, which is so important to patients across the board.

I have some questions here. Mr. Secretary, I know President Biden is noted for saying, "Don't tell me what you value. Show me your budget, and I will tell you what you value." The one thing that I hope that we can all agree on is the dignity and the value of every life, including those Americans with disabilities and debilitating diseases.

For years now, the National Council on Disability, an independent Federal agency, has warned policymakers about relying on quality-adjusted life years. That is QALYs. So, Mr. Secretary, first I wanted to ask, do you agree with the National Council on Disability and the Consortium of Citizens with Disabilities that relying on QALYs is an unacceptable and discriminatory policy?

Mr. BECERRA. Congresswoman, thank you for the question, and I couldn't agree more with you, that we have not done enough to focus on issues of health for folks with a disability. More and more, we are beginning to realize that so many of our loved ones actually have a disability, whether physical or mental. And more and more, we are learning, unfortunately, to our detriment, that we haven't provided the same level of resources and commitment to tackle those types of conditions as we have for the more common types of physical ailments.

And so I will tell you that I absolutely agree with the general concept that we have to do a better job of making sure we are targeting money, and getting things done for Americans with a disability. What I will tell you is that a——

Mrs. RODGERS. So—yes.

Mr. BECERRA. I am sorry.

Mrs. RODGERS. OK.

Mr. BECERRA. Go ahead.

Mrs. RODGERS. Well, I wanted to ask specifically regarding QALYs, the—this policy of a quality-adjusted life year. And I wanted to ask if there would be any provisions in your budget that would give you, as Secretary, the authority to set prices based upon foreign drug prices that are established using quality-adjusted life years.

Mr. BECERRA. Congresswoman, let me say this. I know that the team at HHS can probably give you some particulars on this. I won't profess to be the expert. And so what I will do is just—I will take this matter back to the folks at HHS, and I look forward to being able to respond to you——

Mrs. RODGERS. OK.

Mr. BECERRA [continuing]. As quickly as possible. Again, if it involves drug prices, we are going to do something.

Mrs. RODGERS. OK. Well, we all are committed to bringing down drug prices, prescription drug prices for patients.

One of my biggest concerns with the proposal right now that is before this committee is that, in an effort to bring down prescription drug prices, it includes a reliance on foreign drug prices developed using QALYs. So foreign drug prices that measure quality-adjusted life years, so they are determining the value of an individual, especially an individual with disabilities. And so that is one issue that we really need to address.

I wanted to ask also about Medicare for all, because we continue to hear the drumbeat about Medicare for all. And we know that households with employer-sponsored health coverage would, on average, have more than $10,000 less in disposable income every year with this policy. Medicare for all, or single-payer system, would cost more than 32 trillion over 10 years, a doubling of our projected taxes over that period. And I just wanted to ask if you would commit in your budget to not include a Medicare-for-all proposal that would take away employer-sponsored health insurance from 180 million Americans.

Mr. BECERRA. Congresswoman, I can assure you that the President has spoken with a clarion voice on this issue. He campaigned on this, and everything he has done so far makes it very clear: We are going to work to make sure that we can expand the Affordable Care Act, make it better. And, as a result of the American Rescue Plan, I think every—virtually every American can say it is actually much better, and certainly the million people who have in the last few weeks signed up to get a plan under the Affordable Care Act are showing full proof that the——

Mrs. RODGERS. OK, thank you.

Mr. BECERRA [continuing]. ACA is——

Mrs. RODGERS. I have one more question, one more question.

During your confirmation hearing, Senator Daines said—or you responded to Senator Daines and said, "My job will be to make sure that I am following the law. The Hyde Amendment, which is current law, makes it illegal to use taxpayer dollars to fund elective abortions." Do you continue——

Ms. ESHOO. The gentlewoman's——

Mrs. RODGERS. OK.

Ms. ESHOO. The gentlewoman's time has expired.

Mrs. RODGERS. OK, I will ask that question in writing. Thank you, Madam Chair.

Ms. ESHOO. Thank you. I think we are all going to be submitting questions in writing to the Secretary.

The Chair is pleased to recognize the gentleman from North Carolina, Mr. Butterfield, for your 5 minutes of questions.

Mr. BUTTERFIELD. Thank you, Madam Chair, for convening today's hearing. And thank you to our good friend Secretary Becerra this morning.

Good morning, Mr. Secretary. It is good to see you. I wish we had time to chat this morning, but I am going to get right to it. I would like to focus just a few minutes of my time on the investments in biomedical research put forward in this proposal.

For decades, publicly funded research has laid the foundation for the treatments and cures patients use today. NIH, which has long enjoyed bipartisan, bicameral support, is the largest public funder of biomedical research in the world. And the positive impact of this agency is clear: Heart disease and stroke and diabetes are less deadly, cancer mortality rates are also, overall, on the decline, Americans are living longer, healthier. Yet there is always more we can do to support the health of our constituents.

And so I applaud the administration for investing more resources into biomedical research, and I am really interested in learning more about the proposed Advanced Research Projects Agency. We call it ARPA. I am interested in learning more about this.

Mr. Secretary, the funding request put forward $6.5 billion for the creation of ARPA–H, which I understand is part of a larger $51 billion request for NIH. Can you talk with us about the responsibilities for this new agency?

Mr. BECERRA. Congressman, absolutely. And it is great to see you. We will consider this a 5-minute chat.

What I will tell you is that ARPA–H is meant to complement, not compete with, NIH's basic research. And what we will do is, hopefully, be the springboard to take some of those budding ideas and actually start them off fast track. And we are going to partner far more with the private sector because we know that they are incubating some of these things, as well. But if you don't have a dedicated source of funding for that, with an agency that has a proven track record, as you have said, of success, it is hard to get the private sector to believe that they should make the same investment to try to do this.

COVID–19 is now being attacked by successful vaccines. Why? Because it was a partnership, and we did everything to accelerate those vaccines as much as we could while still maintaining safety. And so ARPA–H gives us a chance to say, on something in the future, we are going to do the same thing.

Mr. BUTTERFIELD. How do you envision the work of ARPA–H coinciding with other NIH institutes, such as the National Center for Advancing Translational Sciences, or the work of NIH in general? How are we going to coordinate these efforts?

Mr. BECERRA. As I said, Congressman, they are going to complement each other because, remember, NIH does the foundational research. Before you can ever run, you have to learn how to walk. And before you can walk, you have to learn how to crawl. NIH is the body that has shown us, scientifically, with facts, how you learn how to crawl, walk, and then run.

What we are simply saying with ARPA–H is, look, this kid is learning how to walk a lot faster than we thought. Shouldn't we invest a little bit more money to find out why it is that that is the case?

And it then complements the work that NIH has already done to let us launch on some of these innovations. Because I guarantee you, Congressman, if you or I had a loved one who was dying of Alzheimer's, we would want to know if there is some innovative, promising research out there, that we could launch it faster.

Mr. BUTTERFIELD. I am glad you mentioned Alzheimer's, Mr. Secretary. The request identifies a few specific diseases like Alzheimer's and cancer and diabetes. And, although I think we can all agree that scientific progress in these areas would be welcome, how might this agency target other important areas, like heart or respiratory diseases, which are also leading causes of death?

Mr. BECERRA. Congressman, that is the big question, right?

And I will tell you, the best response that I can give you is we will follow the science. We won't let politics drive us. It will be the science, because what we want is for Americans to have confidence that, when we launch, it is because we are driven by the data and the science, not because we decided to drive it in the direction of one politician or the other. It has got to be science-driven.

Mr. BUTTERFIELD. This is innovative and exciting. Thank you very much, Mr. Secretary.

I yield back, Madam Chair.

Ms. ESHOO. The gentleman yields back.

It is a pleasure to recognize the gentleman from Michigan, the former chairman of the full committee, a highly valued member, Mr. Upton, for your 5 minutes of questions.

Mr. UPTON. Well, thanks very much, Madam Chair. And Mr. Secretary, and friend, welcome back before our committee. We have got a couple of questions.

You know, as we know, the drug industry helped our country get into this very enviable spot, having access to lifesaving vaccines for COVID–19, in large part because of what we were able to accomplish in this committee, unanimously, when we passed 21st Century Cures, which President Obama signed in December of 2016. And while certainly the industry deserves credit for the speed and efficacy of these medications, and we made sure that there were no safety standards that were removed, while I understand the desire to help other countries suffering from COVID—and look what is happening in India, for sure—I want to make sure that it is a responsible way for all parties, which is why a number of us are very concerned about the administration's recent support of the waiver

to release and transfer the IP for the vaccine, which may have a real chilling effect on innovation in the future.

So Dr. Gottlieb argued that a much more effective means of helping other countries would be to, in fact, ramp up production here, here in the U.S. And I would like to ask, did the administration consider other options besides IP transfers, like what Dr. Gottlieb suggested?

And if so, what were they, and why were they rejected in favor of the IP transfer issue?

Mr. BECERRA. Congressman, first, great to see you again. Thank you for the question, critical question.

I have to first say there is no country that has done more to help the world when it comes to tackling COVID than the United States of America. And that is because of the generosity of Congress, our Federal Government, but most importantly, the American people.

And what we are going to continue to do is help, as we are in India, for example, with the pipeline of PPE. We are doing everything we can to help them accelerate the production of more vaccine. We are going to do our part, as a global citizen and as the most important country and powerful country in the world.

What I will tell you is that, when you have extraordinary circumstances, as we have with this pandemic, you have to apply extraordinary measures. And so we are going to do everything under the sun, the all-of-the-above list, to try to see what we can do to try to help the global community recover. And what we are doing is exactly that. We are going to do it at the same time we want to respect those that make those innovations possible.

And so we are going to try to promote the access to vaccines and promote access to the materials, the PPE, and so forth, that the world needs, but do it the right way, because we understand that this is a partnership, not just among countries but with the private sector, as well.

Mr. UPTON. But did you actually look at going back to the industries, the Pfizer, which happens to be in district, go back to those and ask if they could further ramp up their production that, in fact, we might be able to send those doses, rather than share that IP technology?

Mr. BECERRA. Absolutely. The Biden administration has been having conversations with the industry from the very beginning. And it continues to this day. No action has been taken without having consultation with all those who are stakeholders. And certainly, the industry that has helped create these vaccines is part of the stakeholder group.

Mr. UPTON. I know we have talked a little bit about ARPA–H in this hearing, and Chair Eshoo and others were involved in a meeting with the President at the Oval Office back in March. We are all, all very excited about ARPA–H and, obviously, we want to make sure that it doesn't interfere with the other functions at the NIH and—others that have.

We have made the pledge, as we look to the future, as we look for an update on 21st Century Cures, to in fact include ARPA–H as part of that, to help us get that legislation through. I really appreciate your input to try and make sure that everybody is on the same page. And so we look forward to working on that. We are

very pleased to see that in the President's budget. It was released early on, shortly after, in fact, the meeting that we had in the Oval Office. So we are looking forward to get that done.

I might just compliment Janet Woodcock, the Acting Director of the FDA. She was a mighty big player, as we worked to listen to all the different parties, asking what we could do to expedite the approval of—the 21st Century Cures. I know you know her well, but I just—we appreciate her continuing to work with us and look forward to that relationship, particularly as we look to do an update, 2.0 on Cures.

And with that, Madam Chair, I yield back.

Ms. ESHOO. The gentleman yields back. I join him in his well-earned praise of Dr. Woodcock. She should be the next permanent Commissioner, I think, of the FDA.

The Chair now recognizes Dr. Burgess of Texas for his 5 minutes of questions.

Oh, I am sorry, I am sorry, I am sorry, mea culpa. The Chair now recognizes the gentlewoman from California, Ms. Matsui, for her 5 minutes of questions, followed by Dr. Burgess.

Ms. MATSUI. Thank you very much, Madam Chair, for having this hearing.

And, Mr. Secretary, it is really wonderful to see you in this new role. And I look forward to many other conversations, as we move forward.

Over the past year our Nation has simultaneously confronted the COVID–19 crisis, multiple incidents of systemic racism, and an economic recession. Understandably, these crises have impacted the mental health and well-being of millions of people. In response, the Biden-Harris administration stepped in and requested $4 billion of emergency support through the American Rescue Plan for mental and behavioral health services, including certified community behavioral health centers.

While these actions are important, we must continue to look ahead. This HHS funding request proposes $1.6 billion for the Community Mental Health Services Block Grant at SAMHSA. I do applaud the administration for this historic investment, as we know the block grant acts as an important safety net for some of our Nation's most vulnerable.

Mr. Secretary, the pandemic has been especially disruptive for America's children. How will your Department prioritize the mental and behavioral health needs of children and young people?

Mr. BECERRA. Congresswoman Matsui, I feel like I am at a family reunion, and so forgive me for saying that, but it is so nice to see so many—by the way, there is a lot of disagreements, even among families, when they get into these reunions, so I understand that. But at the end of the day, we are still a family.

Children—you hit it on the mark—I think we want to make sure we do everything we can to address the stresses that our kids have been facing. Sometimes they don't have the same markers, and they don't express it the same way, but we know it is there. And so we have made an historic investment in behavioral health and mental health services. SAMHSA will have an increased budget. We are going to do everything we can to deal with the trauma and

the stress that kids are facing, and we look forward to working with you to make sure we do it right.

Ms. MATSUI. Well, thank you very much for that, Mr. Secretary.

And also, I want to just take a minute to raise an issue that I know you are familiar with: the ongoing actions of drug companies who have chosen to rewrite the 340B program to deny discounts on drugs dispensed through—covered under contract pharmacy. As you know, HHS has issued an advisory concluding that these actions are illegal, yet drug companies have made it clear they do not intend to comply with the law.

I, along with over 220 of my House colleagues. wrote a letter to you earlier this year outlining our strong opposition to these actions. The 340B is essential to providing access to care to low-income and rural patients. I encourage you to take swift enforcement action to put a stop to these efforts to undermine the program. That is my comment to you.

OK, I am on to telehealth now. In the past year telehealth has truly taken root, and we have seen exponential growth in the adoption of virtual care across Americans of all ages, locations, and conditions. As Congress considers permanent telehealth reform, we will need the support of HHS in sharing evidence to assess how telehealth flexibilities extended in response to the pandemic impacted both the Medicare program and beneficiaries.

With that said, Mr. Secretary, do you believe that there are some telehealth regulatory restrictions that Congress and HHS can work together to address in the near term that do not require additional data? For example, the statutory limitations on using telehealth at certain ZIP Codes, or requiring beneficiaries to travel to a clinical setting to receive virtual care.

Mr. BECERRA. Congresswoman, we learned a lot through COVID about telehealth, and there are some things that we can do without Congress having to pass a law to make telehealth work better. We have some flexibility, and we are going to do everything we can, based on what we learned, the facts and the evidence that we learned from COVID.

What I will tell you, though, is that we are going to still have to find that mountain when it comes to broadband access around the country. We have to make sure that we deal with the transportation issues that sometimes make it—even with telehealth—difficult for families. And we have to have the flexibility to put the money where it should go. And so we will work with you, because I think we have all now learned that telehealth can be a godsend for those who don't have easy access to healthcare.

Ms. MATSUI. Right, absolutely. We found that out in this crisis, and certainly broadband access, that is also a purview of this committee too, so we will be working with you. Thank you very much, it was great to see you. And I don't know whether you are my constituent, but it is great—California.

Thank you, and I yield back.

Ms. ESHOO. The gentlewoman yields back, and the Chair now recognizes Dr. Burgess for your 5 minutes of questions.

Mr. BURGESS. I thank the Chair and, Mr. Secretary, welcome to our humble subcommittee.

Mr. Secretary, I have got a couple of questions on the Texas Medicaid 1115 waiver that was originally issued back in 2011, extended in 2017, and then Texas had received in early January a 10-year extension on the 1115 waiver. It wasn't a new program, it was an extension on an existing waiver.

Since then, about 3 months later, the waiver extension was totally rescinded. And this has created a great deal of uncertainty for the State of Texas, certainly for doctors, certainly for patients, certainly for hospitals. It is very difficult for hospitals who are having to plan ahead for their fiscal year and plan for their financial stability and dealing with financial hardships from the pandemic.

So could you tell the committee a little bit about the process involved in rescinding this waiver 4 months after its approval?

Mr. BECERRA. Congressman, first, great to see you, and thank you for the question. It is an important one, because it is not just Texas. There are a number of States who have requests for waivers.

First, it is important to make it clear that Texas continues with its existing waiver, which still has, oh, close to 2 years to run. What we have been discussing with Texas is the extension, which was an extraordinarily long extension of 10 years. Typically, they would run about 5 years. And it dealt with a lot of money.

And so what we wanted to make sure is that, if there is going to be an extension of an existing waiver, that it complies with all aspects of the law. And where we found it deficient was in the public comment that—in the notice and public comment that was not provided for something with so big, in terms of money and for such a long time. And so we are working with Texas to make sure we address their interests and try to make sure that we can move forward with something to extend their waiver.

Mr. BURGESS. Yes, I am eager to know—my discussions with former CMS Administrator Seema Verma, here in the middle of a pandemic, and it was an existing program. And so it was not, in her opinion, it was not unusual to condense the comment period and allow for the extension.

But can you just tell me at what point you became involved in the decision to rescind the waiver?

Mr. BECERRA. Guys, remember, we didn't—the previous administration didn't condense the notice and comment; they didn't hold any notice and comment. There was no opportunity, at the Federal level, to—for anyone to comment on this.

Mr. BURGESS. So when did you become involved in the decision to rescind the waiver?

Mr. BECERRA. Well, HHS has been working on this, CMS has been working on this since before I was confirmed. And we are working on it, simply because it did raise a number of serious concerns about how it was administered and promulgated.

Mr. BURGESS. OK, so here is the problem that I have, Mr. Secretary. There was an Acting Administrator prior to you, Acting Administrator Fletcher. But it seems unlikely that this decision would have—she would have made that decision on her own. Wouldn't that be unusual for an Acting Administrator to make a decision of that significance, just on their own?

Mr. BECERRA. Congressman, I am not—I can't tell you how other administrations have worked and how Administrators at CMS have worked with the Secretary. I am very involved. I try to be very involved with all the different shops within HHS. But I can tell you that, in this particular case, before I was confirmed and had a chance to sit in this seat, work was already being done on these particular types of waivers.

So we continue to work with Texas. We have never not worked with Texas and your delegation, and we will continue to do so. At the end of the day, this is about making sure Texans and all Americans have good healthcare the right way. And we all comply with the law. So I think that, so long as we all can feel like there is public notice and comment provided, that we are providing the right resources to do the job for Americans, we will see an extension.

But remember, this is an extension that would not take place until, what, 2023 or——

Mr. BURGESS. Let me just go back to the question, though. Has an Acting Administrator ever rescinded the State flexibility waiver before?

Mr. BECERRA. I can't answer that, because I don't know what previous Administrators have done.

Mr. BURGESS. And, well, and that would be the other part of the question: If an Acting Administrator has ever rescinded a State flexibility waiver previously, what about a State flexibility waiver granted by a previous administration?

That is, a new administration coming in and going back and saying, "No, you don't have that flexibility waiver, after all." It does seem to me [audio malfunction] and politically motivated decision.

And I do have a number of things, Madam Chair, that I have submitted for the record, and I would ask those be made—ordered at the appropriate time at the end of the hearing.

I recognize the constraints of time, Mr. Secretary, I will follow up with you about this. I appreciate your answers, and I will yield back.

Mr. BECERRA. Thank you.

Ms. ESHOO. Yes, I asked at the beginning of the hearing that everyone stick with their 5 minutes. The gentleman's time has expired.

The Chair now recognizes the gentlewoman from Florida, Ms. Castor, for her 5 minutes of questions.

Ms. CASTOR. Well, thank you, Chairwoman Eshoo, for calling this important hearing.

And thank you, Secretary Becerra, for joining us today. It is great to see you.

It is also heartening to see President Biden's budget prioritize affordable healthcare for American families. It is clear that your aim is to help our communities back home build back better and healthier. And I wanted to share with you what I am hearing from Florida Families First.

They are grateful for everything that is being done to crush COVID–19. It is remarkable that we have now reached the milestone, thanks to the American Rescue Plan and all the hard work of everyone, that we have 150 million Americans with their vac-

cination already. I know we have a ways to go, but kudos to you and everyone at NIH, FDA, CDC, all across the enterprise.

I am also hearing how grateful they are for the Affordable Care Act. You know, ever since it was—it came into law, Florida has led in the number of signups in the healthcare.gov marketplace. But the—due to the American Rescue Plan, now we have been able to lower premiums and lower copays. And it was great to see—it is such a lifeline for families. And Florida had one-third of that million-person signup under the Special Enrollment Period. It was there when people lost their jobs during COVID. It has been there for them.

And I also want to give credit to our navigators back home. They are the ones that are sitting with families, working through all of their options to choose the plan that is best for them. So thanks to HHS for making $80 million available for grants to our navigators. They are very excited about those additional resources, and you can see what it has meant for enrollment.

But COVID–19 has also laid bare a lot of weaknesses. One of them was in data. It was a struggle, especially early on, to understand infection rates, testing. We had Governors like mine that actually tried to hide some of the data. They weren't being transparent. And I really appreciate you all in CDC saying that you are going to use the resources we have provided to update the public health data systems. And I want to work with you on that, going forward.

And then, one other thing before I get to my question, thank you and President Biden for your leadership on addressing the climate crisis. Hotter temperatures and dirtier air and water are impacting the health of everyone, but especially folks on the front lines. And in this budget request you are proposing a new Office of Climate Change and Health Equity to help address the harmful impacts of the climate crisis, especially on communities of color and communities on the front line.

So here is my question. It has to do with junk plans. The Trump administration finalized a rule to expand short-term, limited-duration plans. Of course, you know, these junk plans are not required to comply with the consumer protections in the Affordable Care Act. Oftentimes they discriminate against people with pre-existing conditions, they limit benefits, and they leave our neighbors back home, often, with these huge surprise bills. Even former Secretary Azar agreed, when I asked him if these plans discriminate against folks with pre-existing conditions, he agreed.

So you are aware of how these junk plans operate, Mr. Secretary, aren't you?

Mr. BECERRA. Yes, I am, Congresswoman. And you are absolutely correct.

Ms. CASTOR. So on January 28th, President Biden signed an Executive order directing your Department to review all existing regulations, guidance documents, or policies that undermine the Affordable Care Act, and raise costs on families, and undermine protections for pre-existing conditions. Has your Department undertaken a review of this junk plan final rule to ensure that it is consistent with the policies set forth in the President's Executive order?

Mr. BECERRA. We are undertaking that review, as we speak.

Ms. CASTOR. Terrific. Well, we will be very interested in that.

And also, the American Families Plan, if there is something that we need to do to make sure that healthcare is affordable for families, maybe continuing the policies we enacted in the American Rescue Plan to make sure the premiums and copays are affordable for families. And if there is something we need to do to address junk plans in a lot of these fly-by-night operations that take advantage of our neighbors——

Ms. ESHOO. The gentlewoman's time has expired.

Ms. CASTOR. Thank you, Madam Chair, I yield back.

Ms. ESHOO. The gentlewoman yields back.

It is a pleasure to recognize the gentleman from Virginia, Mr. Griffith, for your 5 minutes of questions.

Mr. GRIFFITH. Thank you very much, Madam Chair. I appreciate it.

And, Mr. Secretary, I appreciate you saying earlier that you were willing to work with all of us, and I do greatly appreciate that.

On May 14th of 2020, almost a year ago, we had a hearing in our committee, and a Michael Bowen of Prestige Ameritech told his story about how he invested in machinery to make masks, et cetera. At that time our country was struggling to find the PPE necessary——

Ms. ESHOO. Would the gentleman suspend for a moment——

Mr. GRIFFITH. Yes.

Ms. ESHOO. Because the clock is not correct. Whomever is in charge of it, please reset the clock so that the gentleman's 5 minutes are—that he has the 5 minutes?

[Pause.]

Ms. ESHOO. Well, please reset the clock, whomever is in charge.

[Pause.]

Ms. ESHOO. Well, why doesn't the gentleman continue? I am sorry. All right, so I will try and time you on my watch. How is that?

Mr. GRIFFITH. Yes, ma'am. I appreciate it. Thank you very much.

Ms. ESHOO. Thank you for talking about Mr. Bowen.

Mr. GRIFFITH. Yes, so Mr. Secretary, Mr. Bowen was very concerned and, you know, he wanted us to guarantee him contracts with the Federal Government because the last time he had done this—geared up and started making more masks—as soon as our crisis was over, or as soon as there was a supply from foreign suppliers, all of the sudden he had no business. The Asian markets shut him out. They put a lot of products onto the market at low prices, and he was not able to compete effectively, and he had to shut down a lot of his equipment. He had to put in mothballs, et cetera. And before he geared it back up he wanted to know, are we going to be buying American?

Likewise, since that time, a number of companies—as a result of the need in this country—a number of companies in my district and across Virginia started making PPE. There is a company that I have been talking with out of Elaine Luria's district, there is a company in my district. I know there is at least three or four in my district that have started, and they are all saying the same

thing: Now that, you know, the Asians have gotten a hold of the situation, they are once again dominating the market.

And, in fact, one of my sources tells me that a recent contract was let where they could have competed just fine, but they weren't even aware of it. And a lot of folks who are supplying the Federal Government and other governments are, in fact, using these sources that are, you know, all approved, et cetera, and then they outsource it to China and other countries. So what are we going to do?

Do we need—and I would submit that we do, but I want your opinion—do we need a Berry-style amendment to say that the Federal Government is going to buy its PPE from American manufacturers? Because if not, every time we have a crisis, we are going to have another boom and bust.

You said earlier you didn't like boom-and-bust funding. That is what these small businesses in the United States are now facing, who were willing to make the PPE, make it at a reasonable cost, and sell it to whomever. But if they are just going to get shut down every time by markets overseas, it doesn't make sense, and it doesn't make sense for a long-term policy in the United States. What say you, Mr. Secretary?

Mr. BECERRA. Congressman, what I say is I am with you in everything you just said. If we didn't learn a lesson from COVID, that too much of our supply was not at our disposal—and, by the way, that is a risk for the life and health of our people—if we have to depend on others, then we are in trouble.

Not only that, why is it that we can't have Americans producing what Americans need?

And President Biden is on top of this. And we have a $10 billion fund that you all made possible through the American Rescue Plan and other initiatives to try to make sure we boost domestic manufacturing. And we are going to be on that one. And I hope you all will work closely with us, because we want to prove to Americans that, if they are willing to make an investment and produce here, we want to support them, because there is no excuse for us to have to go somewhere abroad to get masks, when we got Americans willing to produce them here. And by God, I think this is one that we could take on on a bipartisan basis.

Mr. GRIFFITH. Well, I would agree it can be bipartisan. It is masks, it is gowns, it is gloves, it is everything.

And on January 25th of this year, the President signed an Executive order ensuring the future is made in all of America by all of America's workers, and asked each of the agencies to look into that. Do you know what your agency has found out so far, or what we can do, even before we can maybe get a bill passed?

Mr. BECERRA. We are going to continue to do the work on that. We can report to you back, I look forward to talking to you on that.

But what I can tell you is this, that we are going to make sure that the $10 billion that has been made available for Defense Production Act are accountable dollars, and that Americans take a look at where it went. And so we have to be transparent in the use of that money. And I hope you all will work with us to make sure that we——

Mr. GRIFFITH. Well, I heard from the chair of the full committee that we are going to be doing an ORR——

Ms. ESHOO. The gentleman's——

Mr. GRIFFITH. Is my time up, Madam Chair?

Ms. ESHOO. Just about.

Mr. GRIFFITH. All right.

Ms. ESHOO. I think you have 5 seconds left.

Mr. GRIFFITH. All right. I am just going to say we are going to have to talk some more about ORR, but I would like to see us buying all the PPE for those facilities from American sources.

Thank you. I yield back, Madam Chair.

Ms. ESHOO. Amen to the gentleman. The Chair now recognizes the gentleman from Maryland, Mr. Sarbanes, for his 5 minutes—and just hold for a second.

Whomever is controlling the clock, excuse me for putting it this way, you are doing a lousy job, because it is really messed up. And we need every second. Members need every second they can get to question the Secretary. So would you please reset the clock?

VOICE. It is a technical problem. They are trying to fix it.

Ms. ESHOO. It is a technical problem? Well, you know what? We will keep track on our iPhones here.

Mr. Sarbanes, you are recognized for your 5 minutes. I am sorry.

Mr. SARBANES. Thank you, Madam Chair.

Secretary Becerra, welcome to the committee. It is great to see you, and thank you for coming to discuss the 2022 budget.

Over the past year, obviously, we have made incredible investments in our healthcare system through bills such as the CARES Act, the American Rescue Plan. We have to continue to ensure there is robust funding for programs that will help us recover from the coronavirus pandemic and ensure the long-term viability and stability of our healthcare system. You are, obviously, in a very, very critical position to help facilitate that.

In your testimony you wrote, "Our experiences as children shape the adults we become, and support in childhood can mean success in the futur," and I couldn't agree more with that. I know we share a commitment to ensuring that our young people have what they need to succeed.

One important program for our youth are school-based health centers, and I was proud to have my bill, the School-Based Health Centers Reauthorization Act, passed last December. My pride of ownership in that is really just derivative of an extension of Lois Capps' investment in that issue for many, many years, as you know, being a colleague and, obviously, a fellow Californian.

School-based health centers provide high-quality, comprehensive primary healthcare, mental health services, preventive care, social services, and youth development to primarily low-income children and adolescents across the Nation, play a critical role in helping to reach underserved populations and achieve health equality.

During this pandemic, many school-based health centers have been using telehealth to reach students and provide healthcare services they need. However, it is incredibly important that SBHCs are able to stay open, especially as children come back to school and may require a variety of oral, social, medical, mental health services.

Can you speak to the investments that will be made in school-based health centers or similar programs for our youth in the 2022 HHS budget?

And what additional investments would you recommend to ensure that children receive the health and mental health services they need following the coronavirus pandemic?

Let me just add I look forward to working with you to expand the impact of school-based health centers and be as creative and innovative there as we can possibly be. Thank you.

Mr. BECERRA. Congressman, as usual, we are on the same page on this subject. And I will tell you that HHS will do everything it can to make these school-based health centers successful.

As you know, we don't dictate to the locals how they do things, but we do help them. We assist with resources. We provide guidance. And I will tell you that, if we are smart, we will be able to use some of the investments that are in the President's budget to help with our children, whether it is children who are in need of special care, or whether it is those with a particular disability, or whether it is just making sure we get these kids back on track when they get back to school. We want to make sure that we are supportive.

And fortunately, with the help of Congress, with your work and others' in American Rescue Plan—and if we get the American Family Plan through—I can guarantee you that HHS will be very busy working with our school-based healthcare centers to make sure that kids have what they need to succeed in life.

Mr. SARBANES. Thanks very much. I look forward to that collaboration.

I yield back, Madam Chair.

Ms. ESHOO. The gentleman yields back.

The Chair now recognizes the gentleman from Florida, Mr. Bilirakis, for your 5 minutes of questions.

Mr. BILIRAKIS. Thank you. Thank you very much, Madam Chair. I can't get this to work.

Ms. ESHOO. You sound fine. It sounds like it is working.

Mr. BILIRAKIS. Yes. I can't read that. OK, got it.

Secretary Becerra—thank you, Madam Chair, I appreciate it—during your confirmation hearing you told Senator Daines that, when it comes to laws related to abortion—and I am quoting—"My job will be to make sure that I am following the law." And the question is, do you agree that partial birth abortion is illegal, sir?

Mr. BECERRA. Congressman, thank you for the question. And here, as I said in response to some of those questions during my confirmation hearing, we will continue to make sure we follow the law.

Again, with due respect, there is no medical term like "partial birth abortion." And so I would probably have to ask you what you mean by that to describe what is allowed by the law. But Roe versus Wade is very clear, it set a precedent, and a woman has a right to make decisions about her reproductive health. And we will make sure that we enforce the law and protect those rights.

Mr. BILIRAKIS. OK, and you agree with this particular law?

Mr. BECERRA. Which law are we talking about, sir?

Mr. BILIRAKIS. The law concerning partial birth abortion.

Mr. BECERRA. Well, again, as I said, there is no law that deals specifically with the term "partial birth abortion." We are—we have a clear precedent in the law on the rights that women have to reproductive healthcare. And we—as I said in that confirmation hearing, we will follow the law and protect the rights of all Americans to their healthcare.

Mr. BILIRAKIS. Thank you. So you will follow the law. You will enforce the current law. Thank you very much. I want to get on to the next question.

Mr. Secretary, 93 to 95 percent of the 7,000 known rare diseases have no FDA approval therapy. I think you know this. For those who do have therapy available, the development process takes an average of 15 years. As the cochair of the bipartisan Rare Disease Caucus, I believe we can do better in the United States. And FDA—we know this—OK, do you agree that we can do better, and that one way to do this would be to ensure coordinated, dedicated efforts at the FDA to make sure they are aligned to address the unique challenges rare diseases patients face?

So that is my question, sir.

Mr. BECERRA. Congressman, we should always strive to do better. That is what we believe here at HHS. And I hope you are supportive of our efforts with ARPA–H, because that will allow us to do better.

Mr. BILIRAKIS. OK, and I believe coordination, of course, is the key. I introduced H.R. 1730, the Speeding Therapy Access Today, or the STAT Act, with my Rare Disease Caucus cochair and good friend, G.K. Butterfield. This bipartisan legislation, at its core, would create a center of excellence for rare diseases at the FDA. The Center of Excellence model has been embraced by the FDA in recent years and was originally authorized by the very popular, bipartisan 21st Century Cures Act of 2016.

As we have been seeing with the oncology COE FDA, we know this model can help advance therapies and regulatory science. So the next question is—and I am not sure how much time I have left—but the next—yes, would you like to address that, sir, in any way?

Mr. BECERRA. Congressman, why don't you pose the question, so I know what you would like me to address?

Mr. BILIRAKIS. OK, well, do you agree with the center of excellence, with regard to the rare diseases?

Do you agree we can do better, that one way to do this would be to ensure coordinated, dedicated efforts at the FDA, make sure they are aligned to address the unique challenges rare disease patients face?

Mr. BECERRA. Congressman, I think that is being done, and certainly we can always try to do it better. But I think, at FDA, I think you can say that we have the strongest agency around in the world to try to deal with these innovations and these therapies and treatments that we need for these rare diseases. But we can always do better, no doubt.

Mr. BILIRAKIS. I think this bill will really speed up the process. So I look forward to possibly discussing this with you, along with my cochair and colleague.

Mr. Secretary, the next——

Ms. ESHOO. The gentleman's time has expired.

Mr. BILIRAKIS. Oh, it——

Ms. ESHOO. And again, we apologize to Members for the mess-up with the clock that you see on your screens. But we are keeping track by iPhone, right to the second. So I think the gentleman yields back, we thank him, and the Chair is pleased to recognize the gentleman from Vermont, Mr. Welch, for his 5 minutes of questions.

Mr. WELCH. Thank you very much.

Welcome, and congratulations. Mr. Secretary, I have questions in three areas: one is the 340B program; two is the new ARPA–H program; and three is prescription drug price negotiation.

I know you are concerned about access to healthcare in community health centers and community hospitals. And I have been alarmed, as my local hospitals and community health centers have been, that six pharma companies—I believe illegally—are not passing on the discounts required under the 340B program. Is it the—your intention to enforce continued access to the discounts for our community hospitals and community health centers?

Mr. BECERRA. Congressman, first, great to see you.

Secondly, we are on this one, because we know that vulnerable populations are at risk. And so everyone—I have been saying all along we have to follow the law. Everyone has to follow the law.

Mr. WELCH. OK, thank you. Second, we are all excited about President Biden's $50 billion program, ARPA–H. And, of course, that is going to focus on cures for Alzheimer's, diabetes, and cancer. Is there any consideration to including Lou Gehrig's disease, ALS, in research that would be benefited by that fund?

Mr. BECERRA. Congressman, that is where we are going to be working with you and the White House to make sure we know how to focus the money. We certainly could use more than 6 billion to address all these deadly diseases, but we are going to try to let the science drive us there, because that is the best way to ensure that we will have not just a good result, but one that people will trust.

Mr. WELCH. Thank you. Finally, on prescription drug pricing, there is some dispute here. Pharma companies do not want the U.S. to be involved in price negotiation, yet we have just had a recent example where negotiation was very successful. Government worked in partnership with pharma, we got the vaccine. There was an agreed-upon price: 19.50 per dose. The Pfizer executive is now saying after the pandemic they may go up to $175 per dose.

My concern about healthcare in general is that the cost is too high and not sustainable. It hurts taxpayers, it hurts private employers trying to provide access.

Pharma's concern about price negotiation is that the Government won't be fair. Now, pharma is happy with government providing patent protection, providing a market through the Part D program, providing taxpayer funding through Medicare and Medicaid.

You would play a major role in any kind of price negotiation plan that occurred. How would you address the purported concern that, if the Government negotiated so that we did not continue to pay three times, four times what other countries pay, we would still be the leader on innovation?

Mr. BECERRA. Great question, Congressman. What I will tell you is, first and foremost, failure is not an option here in dropping drug prices. We have to do better, especially when we see the rest of the world paying less than we do for some of these same drugs.

So President Biden has made it very clear he wants to see negotiation of these prices. We can make this a win-win for everyone, including the pharmaceutical industry. We have to make sure that we are partnering with them. We have to have them sitting at the table. But we have to make sure we are moving. There is no reason why Americans should be paying this much their for their prescription medication.

And so, whether it is tough love, or, you know, sitting down and collaborating, one way or the other, we are going to have to drop the prices of drugs. And we want to have everyone who is a stakeholder be at the table when we do it.

Mr. WELCH. Thank you very much, Mr. Secretary.

Madam Chair, I yield back.

Ms. ESHOO. The gentleman yields back. The Chair is pleased to recognize the gentleman from Missouri, Mr. Long, for your 5 minutes of questions.

Mr. LONG. Thank you, Madam Chair.

And thank you, Secretary Becerra, for being here today. Good to see you again.

And the President tasked HHS with a supply chain review of pharmaceuticals and API, among other sectors. At the time, he suggested that these sectors were so critical to the national security of the United States that their supply chains merited additional scrutiny. Last week, however, the White House announced that it was back in the negotiations to eliminate international IP protections for these same products.

Can you share the status of the supply chain review and your views on the importance of ensuring the United States has a strong and innovative domestic biopharmaceutical industry, including our future pandemic response?

Mr. BECERRA. Congressman, first, great to see you again, and thank you for the question. And, actually, this is one where I hope you all will be very interested in working with us on this, because we want to work hard on this one. We want to pounce on this.

President Biden has made it very clear. He made sure in the American Rescue Plan we had $10 billion so we could make sure we improve on domestic manufacturing and production, and we have to make sure that that supply chain is working. And so we hope we are able to work with you, because we know there are a lot of small businesses, innovators out there, who want to be able to compete, and they think they have got a good product. And so, if we are working with you, we will spot them, and we will let them know that we want them in the game.

And so I don't know how better to say it than to say that, on this one, there is no separation, I think, between you and me when it comes to making sure that American manufacturers, American small businesses have a chance to compete to provide Americans what they need to keep themselves healthy.

Mr. LONG. Well, it just seemed like a complete reversal, though, from the administration policy, and that is what I am trying to get

to the bottom of here, when last week, like I said, they announced that they are back in negotiations to eliminate what they said was very critical, IP—international IP protections for these products. So how do you weigh that out?

Mr. BECERRA. So, remember, Congressman, that what the President announced is a way to get a global response to this pandemic. And we are willing to sit down and negotiate to see if there is a way to deal with this.

But everything is still the same until we have negotiated. And once again, the stakeholders—in this case, the pharmaceutical industry, which has intellectual property protections—gets to sit at the table as we figure out how we get vaccines and other COVID responses out as quickly as possible to places like India.

But right now, when we are talking about domestic supply chains, domestic manufacturing, I don't think there is any separation between what you have said and what the President has said in making sure we are targeting American business for a lot of this resource that we are going to put out there to increase the domestic supply and keep that supply chain going with American manufacturers.

Mr. LONG. OK, I will have my staff follow up with yours, because I don't think that I am communicating well, and I don't think I am get my question out to you in the proper form, apparently.

But currently, all of the Provider Relief Funds have been expended by June—or will be expended by June 30th, 2021. I have heard from several hospitals about the uncertainty surrounding this deadline, given the changes in the reporting guidelines. I know the Department of Treasury has issued guidance extending the timeline to the end of 2021 for State and local government funding extended under the CARES Act. Will HHS be issuing an extension to the healthcare providers regarding the use of provider relief funding?

Mr. BECERRA. Congressman, we are going to be working hard to make sure that we provide those healthcare providers who work very hard with the resources they need. Some of those folks have asked for an extension. We are looking at all that very, very closely.

What I will tell you is that we are, again, going to be driven by the facts in this case to make sure those providers who have a need get those needs addressed. That is why you all passed the money, and that is why we are going to make sure that we can dispense it in a way that is not only accountable, but it really does go to those who need it most.

Mr. LONG. OK, thank you. And President Biden's administration announced a $6 billion investment in community health centers to expand access to vaccines in underserved communities. However, the current Medicare FQHC reimbursement system may create a barrier to access a COVID–19 vaccine.

FQHCs are not paid separately for vaccines, but are reimbursed by CMS 12 to 18 months after the fact. This has been an ongoing problem for flu and monoclonal vaccines that have now reached critical levels in the administration of COVID vaccines to Medicare patients.

Are you or will you commit to working with our health centers to address this issue so that they have the tools and resources that they need to provide expanded access to these vaccines?

Mr. BECERRA. We have always had a good relationship with the community health centers, and intend to have that, as well. So we will work closely with them. Yes, sir.

Mr. LONG. OK, thank you——

Ms. ESHOO. The gentleman's——

Mr. LONG. It is good to see you, and I yield back.

Ms. ESHOO. The gentleman's time has expired, he yields back. It is a pleasure to recognize two doctors coming up from our committee: the first, Dr. Ruiz of California, followed by Dr. Bucshon of Indiana.

So you have 5 minutes, Dr. Ruiz, for your questions.

Mr. RUIZ. Thank you very much.

Secretary Becerra, thank you for being here. I want to touch on a few different topics today.

First, I would like to commend the administration for prioritizing vaccine equity and the distribution of vaccines into our underserved communities. As a doctor and public health expert vaccinating my constituents in underserved communities, I can say firsthand that President Biden's Federal Retail Pharmacy Program, mobile clinics, and direct vaccine allocation to FQHCs are effective. However, we still have a ways to go in reaching a national herd immunity.

And I am concerned by reports that vaccine rates are plateauing, while around 50 percent of Americans still need to be vaccinated, and with underserved communities still having low vaccination rates. In fact, the Desert Sun newspaper reported this week, after analyzing California, HHS, and Census Bureau data, that vaccine rates are still significantly higher in the White, older, wealthier ZIP Codes in my district by up to 30 percent, compared to poor, younger, minority communities. While some of that could be because older people were first to get the vaccine, older individuals in underserved communities still lag behind. And all ages have been eligible since mid-April.

Secretary Becerra, since we have reached a plateau in vaccination rates, has there been a shift in the administration's efforts and methods around reaching the individuals that have not yet been vaccinated to address barriers like time, language, and transportation restraints?

Mr. BECERRA. Congressman, it is great to see you, and the answer is absolutely yes, there have been changes made. In fact, later this week I will be going to a rural community in California where there will be a small vaccination clinic targeting folks who are most underserved and the most difficult to reach in some of our rural areas.

Mr. RUIZ. Thank you, and I think that is very, very critical, to partner with local communities and taking the vaccines to the people, and I applaud your efforts in doing that.

So now, pivoting to an issue that this committee worked on prior to the pandemic, which is surprise billing, my Republican colleague, Dr. Bucshon, and I worked with several of our colleagues in a bipartisan manner to craft a solution that would, first and

foremost, protect the patient from surprise medical bills and to create a solution that is fair to both providers and insurers, which included a baseball-style arbitrator, independent dispute resolution process that this committee and Congress adopted. And so I would like to ask you some questions regarding the implementation of the law.

So first, regarding the IDR process, I urge the administration not to weigh any one factor to be considered by the arbitrator more heavily than the others. The legislation signed into law represents a balanced approach that treats providers and insurers equally and does not favor one party over another. I am concerned that, if any of the factors are weighed more heavily than the others, it will tilt the balance, resulting in an unfair system that will unintentionally lead to a benchmark rate which runs counter to congressional intent.

Second, it is my understanding that HHS is meeting with stakeholders and requesting their input. I appreciate the administration soliciting feedback. I strongly urge you to move forward with a proposed rule that includes a full public comment period, so that the process is transparent and all stakeholders have an opportunity to comment, to provide feedback.

Mr. Secretary, have you made a decision on the rulemaking process and whether it will include public comment?

Mr. BECERRA. Congressman, thanks for all the questions. We are going to make sure that people have an opportunity to know what is going on with these rules. We are going to try to move them as quickly as we reasonably can.

What I will tell you is this: Paramount will be making sure that the patient is not—doesn't get in the mix of the—any fight that may exist. We are not going to weigh any side more than another, and we are going to make sure that we launch these committees as quickly as possible. That will help us make these decisions, because everything you have said is accurate.

Mr. RUIZ. Thank you very much. And for my final question I would like to ask about an issue near and dear to me: advance appropriations for the Indian Health Service.

As you know, IHS is severely underfunded and continuously struggles financially, which hurts patients' access and care. So, Mr. Secretary, can you talk about the benefits of advance appropriations and how it will help the IHS better serve our Tribal communities?

Mr. BECERRA. Our Tribal communities, as you know, Congressman, have been underfunded, severely underfunded, for too many years. President Biden has now made a major commitment to restore some of that funding, but he has also made the commitment that Indian country has been asking for for a long time, and that is that they be treated, when it comes to health, the way we treat every other aspect of healthcare for all other communities, and that is that they have predictability in their funding, moving forward. And that is why the advance appropriation is so critical. And that is why, with your help, we will get that done.

Mr. RUIZ. Thank you very much, Mr. Secretary. I yield back my time.

Ms. ESHOO. The gentleman yields back.

The Chair is pleased to recognize the gentleman from Indiana, Dr. Bucshon, for your 5 minutes of questions.

Mr. BUCSHON. Thank you, Madam Chairwoman, I appreciate that.

Secretary Becerra, thank you very much for appearing before the committee today. To show pretty significant bipartisanship, I am going to focus on surprise medical billing, as my colleague Dr. Ruiz has just mentioned, and particularly the agency's implementation of the No Surprises Act. As you probably know, Dr. Ruiz and I, as he mentioned, worked to advance legislation into law that is both fair and balanced and, most importantly, as you mentioned, takes the patient out of the middle of all of this. That is the key.

The No Surprises Act establishes an independent dispute resolution process that allows both sides the opportunity to present a list of criteria to an arbiter to make their case. The list includes, among other factors, the median network rate, market share, good faith/bad faith efforts, and prior contracted rates.

Some—in my opinion, biased—economists have suggested subverting the intent of Congress by suggesting HHS should implement the long-awaited—overemphasizes a low benchmark or qualified payment amount in the IDR process. Congress agreed to a deal that carefully balances a host of important arbitration criteria to make sure that no side has an unfair advantage.

I want to echo what my colleague Dr. Ruiz's concern with a letter—in a letter that was sent, asking for any rule promulgated by HHS to follow congressional intent, in which the factors specified in the law must be weighted equally to ensure that patients have access to affordable and quality care.

So my first question is, generally speaking, how do you intend to make sure the process is fair and balanced and doesn't just revert—reverting to a benchmark in practice—we don't want that to happen—which this compromise framework in the No Surprises Act was intended to avoid?

Mr. BECERRA. Congressman, thank you for the question. And first, I have to just say thank you for the work that you all did to get this done. And now we—it is our job, as you said, to follow the intent of Congress on this.

And so the most important thing we can say is what you said. We have got to take the patient out from underneath the weight of these disagreements, and we make sure that that will be the case. When we move forward with the committees that will explore these things, we are going to make sure that we have taken patients into account.

But to your point, we are not interested in favoring one side over the other in the dispute. What we do want to make sure is we take the patient out of the dispute altogether, but then we are going to be even-handed when it comes to the dispute itself. And so the factors that will go into that, that is—we are going to hear from everyone to figure out how we can have a balanced approach. And that is where your input will be important, because you all were the minds behind this, and we hope you will provide us with a good input as we move forward to get this up and going.

Mr. BUCSHON. I appreciate that, because we do feel like congressional intent is that all the factors be weighed equally. And the law——

Mr. BECERRA. We are with you.

Mr. BUCSHON [continuing]. You, as Secretary, along with consultation from Treasury and Department of Labor, define what the median network rate is—in-network rate is. Can you guarantee that the data to calculate the median, in-network rate is independent, valid, and transparent?

Mr. BECERRA. That is our goal, Congressman, and you will get to see the work that we do to make sure that is the case, and hold us accountable.

Mr. BUCSHON. I appreciate that, because the transparency, I think, at agencies is as important to Members of Congress, of course.

Nothing is more frustrating—and you know this, because you were here for a while—when you work on legislation and then you see that it is implemented by an agency, and you have questions about whether or not that has followed congressional intent. So, if anyone understands that, it would be you.

The No Surprises Act is clear that, no later than 30 days after the claim is submitted to a health plan, that the plan must issue an initial payment or a denial. How will you protect physician practices in the event that health plans fail to respond to the claim, that the claim is being considered—respond to the claim that the claim is considered de facto accepted by the health plan? Does that make sense?

Mr. BECERRA. I think I understand——

Mr. BUCSHON. Basically, how do you hold the plans accountable if they don't address the claim in a timely manner?

Mr. BBECERRA. Yes, and that is where the dispute resolution process will be critical, because there have to be teeth, right? And you understand this because, at the end of the day, when a decision is made, there has to be followthrough, especially by those that are providing the payment, the reimbursement.

And so I hope what we will be able to show you is that we come up with a system that actually is accountable, and shows results because, at the end of the day, the public is not going to believe us, that we meant this, if we don't do it right. And while we keep them out of the dispute, at the end of the day somebody has to get paid.

Ms. ESHOO. The gentleman's time has expired.

Mr. BUCSHON. OK, thank you, Madam Chair.

Ms. ESHOO. Thank you.

The Chair now recognizes the gentlewoman from Michigan, Mrs. Dingell, for your 5 minutes of questions.

Mrs. DINGELL. Thank you, Madam Chair and Ranking Member Guthrie.

And Mr. Secretary, it is great to see you. I want to thank you for being here, and I really look forward to working with you on so many issues that we both care about, from the opioid crisis, the high prescription cost of drugs, to clean, accessible water. But today I want to talk about strengthening our Nation's readiness for the public health crisis.

As you know, public health funding follows a pattern of panic and neglect, where large amounts of money are invested during a crisis. And then, once the crisis is over, funding is not adequately maintained. I think that maybe this pandemic has opened our eyes to the deadly shortcomings of this pattern. And this committee has worked to not only shore up the current needs but shed light on the realities of the needs to come, whether planned or not.

So, Mr. Secretary, how is the administration's funding request for this year reflective of the Department's effort to break this cycle and achieve long-term public health preparedness sustainability?

Mr. BECERRA. Congresswoman, great to see you, and a critical question, because we saw, through COVID, how the stockpile needs to be modernized.

I will say this. First, we have to make sure we have got the resources to make sure we have got the right amount of the supplies, that we have a supply chain that works. And so we are going beyond just putting product in storage and making it available. We are going to go into taking a look at how we actually distribute.

You know, we need visibility on that supply chain, and we need to have accountability, as well. And, as we discussed earlier, to the degree possible, we should make sure that Americans are providing the product that we are using in that supply chain. And so we are going to work as hard as we can. The resources come through. I guarantee you what you are going to find is that we are going to lift up the strategic national stockpile in ways that make it a 21st century process.

Mrs. DINGELL. That is great, and I think we need to bring that supply chain back to this country as fast as we can.

And just as an aside, I would also like to say that, in this recent surge, my nurses still lacked from—PPE supplies, and did not have N95 masks.

So the funding request includes 905 million for the Strategic National Stockpile for supplies and maintaining restructuring efforts initiated during the pandemic. What are the Department's immediate priorities for the stockpile, and how will this be—funding be used for the critical improvements we need right now?

Mr. BECERRA. Congresswoman, some of that is pretty basic. We have to make sure we know what is in the stockpile. We have to know if it works and we have to know if it really meets the needs of the 21st century crises, the national pandemics that we might face. And so we have a lot of work to do.

We have to make sure that we can work with the technology that lets us move instantaneously, because we know that it is not just a matter of having it in storage, it is getting it where it needs as quickly as possible because lives are at stake. So it is, essentially, all of the above, but we are going to have to do a scrub to make sure the SNS is really working for Americans the right way.

And so I look forward to working with you on this, because I think we have learned that this is going to be a critical component of being able to respond adequately and quickly to any future healthcare crisis.

Mrs. DINGELL. I am going to sort of ask you my last two questions, because I don't have that much time, but I really want to work with you on this.

I mean, what should we, as Congress, be considering as we conduct oversight on the COVID–19 response and consider possible legislation to address failures in preparedness?

But also, as somebody who became—my district became the arsenal of health at the last minute, but there were startup problems, but they were doing both PPE equipment and the ventilators. What is the—how do we examine the role for more private-public partnerships in purchasing, securing, and stockpiling PPE?

And what, if any, SNS capabilities can be better managed, maybe even at the State level than the Federal level?

Mr. BECERRA. Congresswoman, I think we learned a couple of things.

One, we need to have better communication and coordination with the State and local partners that we have. They need to have a better sense of what we have got in the stockpile, how it is going to be dispersed, what they can expect.

We also need to work with them a little closer so they know that we have to know that there will be results. If they want something, we have to know it is going to go to the right people at the right time. And so we have to have far more coordination.

You know, there was a lot of disjoined activity occurring at the very beginning of this pandemic. And it wasn't clear, you know, if the left hand was guiding the right, or vice versa. We can't afford to have that happen. So better communication, better coordination, and stronger partnerships, not just with our local and State government partners, but with our private sector partners, as well.

Mrs. DINGELL. Thank you, Mr. Secretary. Twenty-four seconds doesn't let me ask another question, so I will yield back. But it is great to have you back.

Mr. BECERRA. Great to see you.

Mrs. DINGELL. Madam Chair, I yield back.

Ms. ESHOO. The gentlewoman yields back. We thank her.

It is a pleasure to recognize the gentleman from Oklahoma, Mr. Mullin, for your 5 minutes of questions.

[Pause.]

Ms. ESHOO. Can you hear me? Am I unmuted?

Mr. MULLIN. No, I was on mute.

Ms. ESHOO. Oh, I see, OK.

Mr. MULLIN. I started talking, and I forgot to hit the little red button that says "unmute." But, Madam Chair, thank you so much, and Mr. Secretary, thank you for being here.

Last Congress we appropriated $47 billion for COVID testing. Do you know how much of those funds still are available?

Mr. BECERRA. Congressman, I don't have that number off the top of my head, but if you like, I could get back to you on that, or your staff.

Mr. MULLIN. Yes, I would appreciate it. We are just trying to figure out if—you know, what the funds are going to be used for, or if Congress is going to need to reappropriate those dollars. If—and if we are not going to be testing—because I believe we—if I am remembering this correctly, we appropriated an additional 50 billion that was provided in March for COVID. And the administration is saying now they won't need but about 13 billion of that, which—that is a—you know, we got 37 billion still sitting there.

Do you have any idea, you know, what the intent is going to be with your office on how to use those funds?

Are you able to use it in a different way or, once again, is Congress going to need to reappropriate these?

Mr. BECERRA. Congressman, excellent question. And what I will tell you is that, as you watch what is going on in India and we learn more about these variants that are popping up, we are not done, and no one should get any impression that we are done tackling COVID or whatever comes—you know, the mutants that come from—mutations that come from COVID. And so we have to continue an aggressive testing strategy. We have to continue to make investments to prevent the spread of COVID and its variants.

And so I will tell you that, while we—I can't tell you exactly how much money is there right now, and I can get back to you on that, and we could certainly make sure that we are keeping you abreast of what the plans are to make sure that we continue to tackle COVID and whatever comes next.

Mr. MULLIN. Well, I have no doubt, you know, your dedication to tackling COVID. It is just, you know, with that much money sitting there, what we don't want to see is it is just sitting there, and it doesn't go away. What we have—we have a lot of accounts throughout government that—money is just sitting there that Congress appropriated for, and it is—it can't be used.

So if there is a better way for us to appropriate it—for instance, as Mrs. Dingell was saying with PPE, if we need to reappropriate it for the Strategic Stockpile, if we need to use it more focused on rural areas—and that is an area—if we need to go to the—take it to the border—I mean, right now I think the President requested $4.3, roughly, billion for a refugee resettlement camp.

And, I mean, kind of a question there: Does that 4.3, does that account for what is going on with the Biden border crisis right now on the southern border and the influx of the illegal immigrants?

Mr. BECERRA. So I think you asked two different things there. If you want, I can—on the question about the resources for testing, I will tell you that we can stay in touch with you. We appreciate your interest and concern. We are going to make sure that, whatever resources we have, we will use not only appropriately but transparently. And so we can stay in touch on how we are making the investments to keep Americans safe.

On the issue of the border, Congressman, can I ask you to repeat that question one more time?

Mr. MULLIN. What I was—the reason why I was comparing the two is, do we need to reappropriate those dollars to what is happening on the border, with the crisis that is taking place there?

Because the President authorized $4.3 billion to—for the refugee resettlement. And with the influx of the illegal immigrants that is coming across and the high amount of those that are being detained and not being tested, do we need to reappropriate funds to go to that sector?

Mr. BECERRA. Congressman, as you know, we—at HHS we have many obligations.

Mr. MULLIN. Right.

Mr. BECERRA. One of them is to make sure we continue to test the American public for COVID. We will continue to do that, and

we will make sure that we are in touch with your office on the resources that it takes to do that.

When it comes to the migrant children at the border, we have a responsibility to make sure that they are—their well-being is cared for for however long they might be in this country and whatever their ultimate status will be. Our job at HHS is different from DHS. We have to provide the care that we expect for any child. We will do this and, obviously, need resources to make that happen.

Mr. MULLIN. Mr. Secretary, it is not just that. It is the adults too. I mean, I fly through Dallas almost every week. And when you go through Dallas, what you will see is someone walking around with a manila envelope and a card that says "No English." And they are being shipped to wherever. And it could be the day before when they were actually apprehended on the border, and there is no way they can be tested that quick.

And so before we are letting these people, literally, be deported—or be transported, I mean—all over the United States, I think it would be wise for us to make sure they are being tested. And there is no way they are being tested right now. And so that is what I am getting at. Should we reappropriate those funds to go towards those testing?

Mr. BECERRA. Well, I would question the premise that they are not being tested, but I want to make sure that it is clear we have to put the resources where we need them. And at HHS, we—whether it is the testing issue, or with the children at the border, we have—together a responsible proposal to get both of those things done.

Mr. MULLIN. Right. I will yield back, but I would check into the testing——

Ms. ESHOO. The gentleman's time—yes.

Mr. MULLIN. Thank you.

Ms. ESHOO. The gentleman's time has expired. The Chair is pleased to recognize the gentlewoman from New Hampshire, Ms. Kuster, followed by Mr. Hudson.

So you are recognized, Annie, for your 5 minutes.

Ms. KUSTER. Thank you so much, Madam Chair.

And Mr. Secretary, wonderful to be with you. And thank you for your—today. Welcome back to the People's House, and congratulations once again on your confirmation as our Health and Human Services Secretary.

The funding request for HHS put forward by the Biden-Harris administration is exactly what we need in this moment to address the many challenges facing our country.

One challenge I look forward to working with you and other HHS agency officials on is how we can address the increasing number of drug overdoses and expand access to prevention, treatment, and long-term recovery services for those suffering from substance use disorders. An important priority of mine this Congress is identifying ways to expand access to care and treatment within incarcerated settings.

Last Congress, Senator Booker and I partnered on new bipartisan legislation, the Humane Correctional Health Care Act, which would allow Medicaid to follow our justice-involved population dur-

ing their time in Federal prison in order to provide much-needed mental health and substance abuse treatment.

A catalyst to our recidivism crisis is that our justice-involved population does not receive adequate healthcare, particularly when it comes to treating mental health and addiction, leaving these vulnerable Americans with the same substance misuse disorders when they leave prison as when they arrive. And we all act shocked. We are not shocked when they go back to their diabetes. We shouldn't be shocked that their untreated mental health and substance abuse problems persist.

Senator Booker and I are working on reintroducing bipartisan legislation. I would welcome the opportunity to work with your Department and CMS on this critically important public health issue.

Now, with respect to the HHS budget, I was pleased to see it includes $10 billion across your agency to combat the substance misuse epidemic, which I understand is nearly a $4 billion increase over the past fiscal year. I applaud this bold investment. I want to ask about your goals for this funding.

Secretary Becerra, this is a significant amount of funding proposed to fight the drug epidemic. How will this be spread across your agency?

And what actions do you plan to take with these investments?

Mr. BECERRA. Congresswoman, wonderful to see you again, and excellent question. And if we are able to continue with the resources that we have seen so far—and thank you for the help in getting some of those resources in the American Rescue Plan—we will be able to let SAMHSA at HHS really take the lead to try to address some of these concerns.

And we know, because of COVID, it is an even sharper concern. Some 81,000 Americans died this past year from drug overdoses. And I think that is the largest number we have seen in quite some time. And it is clear that there are a whole bunch of Americans who are very stressed, and they need that assistance. So we are going to get out there and work with State and local partners the best we can.

But SAMHSA will take the lead, and we will try to supplement what we can with the resources that our State partners have. We are going to try to be innovative, I will tell you that. We are going to try to make sure that we allow for those medically assisted treatment programs to get out there and do their job.

We want to make sure that Americans know, especially the young population knows, that we want to catch them. We want to catch them before they fall completely. And I think, working with you, we can make a real dent in this and prove to Americans that we are serious about tackling this.

Ms. KUSTER. Well, thank you. And on behalf of all the members of our bipartisan Addiction and Mental Health Task Force, we look forward to working with you, as well.

We know that only a fraction of patients with substance use disorders have access to [audio malfunction]. Can you discuss how—improve access to evidence-based treatment, including in rural communities like my district in New Hampshire?

Mr. BECERRA. And that is where Congress can—as I mentioned, it is important that we work with our State and local partners, be-

cause they are the ones that are going to be implementing on the ground.

I will tell you, as my—in my former work as the attorney general for our State of California, we worked very hard to get to the point of actually having a major settlement with some of these drug manufacturers and drug distributors of opioids, to try to help make sure we put money into our communities to address the abatement needs of a lot of these jurisdictions, and to try to go out there and provide services.

If we are smart, we are going to work closely with our partners to make sure that they take that settlement money, we take the money that is coming out of the American Rescue Plan, and we are applying it so that we are actually providing on-the-ground services quickly to a lot of our families.

And so we have an opportunity to do something we haven't done in a long time, and that is actually make a dent in this crisis.

Ms. KUSTER. Well, thank you so much. And with that, I yield back.

Ms. ESHOO. The gentlewoman yields back. We want to put more than a dent in it. We have dents, but we could—under your leadership, we want to rid ourselves of this.

The Chair now recognizes the gentleman from North Carolina, Mr. Hudson, for your 5 minutes of questions.

Mr. HUDSON. Thank you, Madam Chair.

And Mr. Secretary, welcome. Thank you for your time today. Like many Americans, I am concerned about the worsening crisis on our southern border. Data shows that crossings, unaccompanied minors, and drugs like fentanyl encountered at the border are at record highs. In fact, it was just reported by Border Patrol that apprehensions in April reached the highest total in 20 years.

I recently visited the border and saw this humanitarian, public health, and national security crisis firsthand, specifically at the Donna migrant facility designed for 250. They were holding 3,500 children inside. I hope you agree this is a real crisis. And it appears the Government is running out of capacity to house more than 20,000 minors, a record-high number. This week I read a report that HHS is considering sending hundreds of those unaccompanied minors to a North Carolina city.

And, Madam Chair, I would like to enter into the record an article from the Washington Examiner entitled, "North Carolina City Could Be Next to House Unaccompanied Minor Children."

Mr. Secretary, can you confirm if this report is true?

Have you already sent or are you planning to send minors to North Carolina?

Mr. BECERRA. Congressman, thank you for the question. And first, let me respond by saying that we are always trying to make sure that we are providing a safe and a legal shelter for the kids who are in our custody. And so we do. And as you mentioned, there are several thousand of them. Because it is our responsibility to take these kids from the Customs and Border Patrol detention centers and actually provide them with the type of housing that is expected for a child.

But I will tell you that there is no plan that we have to shelter children in North Carolina. We are always looking for sites where

we can provide the type of safety and security that children need. And we have sites throughout the country. But there is no plan that I could tell you right now to shelter children in North Carolina.

Mr. HUDSON. Thank you for that answer.

You know, currently, if an American citizen wants to fly from Mexico to the United States, we are required to have a negative COVID test first. Before your agency sends migrants to some of these locations you mentioned around the country when you receive them from the Border Patrol, are they being given a COVID test before they are put on public transportation?

Mr. BECERRA. Congressman, they are absolutely being checked, because the last thing we can afford to do is have a spread of the virus at the locations where we are housing a number of these kids.

And, as you probably are aware, we don't—we have them in quarters that are quite tight at times, and so we have to protect their safety and the safety of the Americans who are working with them. And so we absolutely make sure they are tested before they come to us.

Mr. HUDSON. So 100 percent of these minors that you are receiving of the 20,000 are being tested before they leave from the border location to enter the other places in the United States, 100 percent are being tested?

Mr. BECERRA. Absolutely.

Mr. HUDSON. Well, that is comforting. I appreciate that.

And so, in March, I sent a letter to our North Carolina Governor and to the DHS Secretary because there was an article that was saying that migrants were not being COVID tested, and some that actually were tested, and tested positive, were then being put on buses. And one of the individuals being interviewed for the story said that he had a ticket to leave the next morning for North Carolina. So that is really where my concern is coming from, that—you know, that these individuals, if they are testing positive, were being put on transportation anyway.

Could you tell me, when you were testing these unaccompanied minors, if they have a positive test, what is then being done with that individual?

Mr. BECERRA. Great question, Congressman. We have to make sure we isolate them from the rest of the population, which is one of the reasons why it has been such a tough assignment, because we have to make sure we have the space to accommodate these kids.

Remember, we are still under a legal obligation, as a government, to move these children out of CBP's custody within a certain amount of time, 72 hours. And so, whether the child is positive or not, CBP is under a mandate to move them, and they come to us. And so we have to make sure that any child is safe. If there is a COVID-positive child, we have to make sure they are safe but that they are also not spreading the disease. And so we make accommodations, which is not easy. It is not cheap. But we do it, because that is the right thing to do.

Mr. HUDSON. Well, what I learned at the border, at the Donna facility, is there were children who had been there 28 to 30 days.

And so, I—you know, I imagine—you know, I am hopeful that you are able to comply with the law. At the time that wasn't happening.

Mr. BECERRA. Can I just—just to give you a sense, as of yesterday, there were zero children in Customs and Border Patrol custody who had been there more than 72 days—72 hours, excuse me, more than 72 hours. Zero kids. But you are absolutely right, there was a time when they had in their custody quite a few. But that has now changed. There are—the average time that a child is now in Customs and Border Patrol custody is 25 hours.

And so, Congressman, what I can tell you is we at HHS have worked very hard to make sure that not only do we relieve the pressure that CBP was under in housing these kids, but we do it the right way, we do it legally, we do it responsibly. And while it takes some money and it takes some time, we are going to do it right.

Ms. ESHOO. The gentleman's time has expired.

Mr. HUDSON. Thank you.

Ms. ESHOO. I thank the gentleman.

Mr. HUDSON. Thank you, Madam Chair.

Ms. ESHOO. Thank you. The Chair is pleased to recognize the gentlewoman from Illinois, Ms. Kelly, followed by the gentleman from Georgia, Mr. Carter.

Ms. KELLY. Thank you, Chairwoman Eshoo, Ranking Member Guthrie, for your leadership and opportunity to serve an informed discussion on the Department of Health and Human Services' budget priorities.

Secretary, it is always good to see you. Thank you for testifying before the committee today. I would like to discuss the issue of maternal health and maternal mortality in the United States.

As noted in the administration's budget request, the U.S. has one of the worst rates of maternal mortality among developed countries in the world. In 2017 the U.S. recorded a maternal mortality ratio of 17.4 deaths per 100,000 pregnancies, ranking last among industrialized countries. The numbers are far worse for Black women. In the same year, Black mothers experienced a maternal death ratio of 37.1 deaths per 100,000 pregnancies, more than twice the rate of White mothers. The causes of death vary, but it is clear they are widely inequitable outcomes for maternal health in our country.

I fully support your request to increase investments in maternal health. The HHS funding proposal requests increased funding for maternal mortality review committees, rural maternal healthcare, implicit bias training for clinicians and health workers, and State pregnancy medical home programs. Many of these proposals have also been priorities for the E&C Committee, and I believe these provisions are critically important to addressing the maternal health crisis.

Secretary Becerra, improving maternal health outcomes requires assessable quality, preconception, prenatal, delivery, and postpartum care. How could the investments the administration has requested improve maternal healthcare and narrow these persistent inequities we see in maternal health outcomes?

Mr. BECERRA. Congresswoman, great to be with you, and thank you for the important question. I am glad you asked this question,

because too many Americans don't realize that we have a maternal mortality crisis in America. It is just that it is hidden. It only occurs in certain communities, but it is a crisis. And we are going to tackle this.

And I hope that we are able to work with you and others who are interested, because we are going to use an evidence-based intervention approach. We are going to go where we know the crisis exists. We are going to use the types of procedures and treatments that we know have worked.

By the way, my wife will salute you for having asked the question, as a high-risk perinatologist essentially dealing with these types of crises. She wants to know that we are making the investments. And what we are going to do is go into the communities.

And by the way, part of this is not just on the medical side. Part of this is just making sure a woman has access to the type of information and services she needs during the pregnancy to make sure that she doesn't end up having a crisis on delivery.

And so we are going to work closely with those who know how to do this, and I guarantee you we are going to make a difference. That $200 million is going to be money well spent.

Ms. KELLY. Thank you.

Last Congress the House passed the Maternal Health Quality Improvement Act in an overwhelmingly bipartisan fashion. The bill included grants for implicit bias training similar to the proposals in the budget request as well as additional provisions to address maternal health and training for healthcare providers.

Unfortunately, this bill did not become law last Congress, but I continue to believe these policies are critically important. Can you discuss the value of implicit bias training for healthcare providers, especially in the context of maternal health?

Mr. BECERRA. And here is where Carolina, my wife, could do a far better job because she has actually witnessed this, but what she would tell you is that, oftentimes, when a woman—especially a woman, but it could be anyone—comes in, if you don't have a provider, a physician who has—or other kind of provider who hasn't really experienced the type of circumstance that some of these—some of the patients come in with, it is tough. And we use our—these biases that we don't even know about, these implicit biases to make judgments and decisions about the healthcare for these patients.

And so what we need to do is just understand that we need people who have that sensitivity. We have to provide the training. But more than that, we have to give the patients some control over this to make sure that they know where to go to get the care that they need. And that is where, if we tackle the implicit bias the right way, what we are going to do is actually ensure a better outcome for not just the patient, but, if it is a woman who is pregnant, for the future of our country.

Ms. KELLY. Any other additional policies you want the committee to consider?

Mr. BECERRA. Well, I——

Ms. KELLY. You could send them on, if you don't have them off the top of your head.

Mr. BECERRA. Well, listen, Medicaid has been relied on by so many of these mothers that we are talking about. If we could just make sure that we continue to support Medicaid, continue to urge some of those States that have not expanded their Medicaid to do so, we would really be dealing with this.

And remember, we have now put a challenge out there. If there are States that want to expand care postpartum for a woman from 60 days to a year, we are with them and we will provide them some additional support.

Ms. KELLY. Well, thank you so much. I look forward to working with you. I am proud to say Illinois was the first State to do it, so—with your help.

Thank you so much, and I yield back.

Ms. ESHOO. The gentlewoman yields back. And Mr. Secretary, no Member of the House of Representatives has done more on this issue than Ms. Kelly. So she is our leader on this.

I understand that two Republicans, Mr. Carter of Georgia, Mr. Dunn of Florida, are not going to be questioning.

So I am going to move to recognize Mr. Curtis of Utah for your 5 minutes of questions, followed by Ms. Barragán of California.

Mr. CURTIS. Thank you, Madam Chair.

And Mr. Secretary, it is nice to be here with you today, and I regret—I have not been in Congress long enough to know you from your DC life, but it won't surprise you that you made a few headlines as attorney general in California, and I have heard of you. In that role you have led a charge against the previous administration's efforts to expand access to association healthcare plans. And I would like to discuss those for a minute.

Although you have led that charge, research shows that premiums in States that allow these plans decreased, enrollments in ACA-exchange plans increased, and the number of new plans offered in these marketplaces increased by 61 percent. Those are all good numbers. However, the individual marketplace, prior to the actions taken by the previous administration, which you oppose, tell a different story, and show an increase in premiums by 105 percent.

Would you agree that, overall, philosophically, more plan offerings will strengthen our healthcare system and drive down costs, which is clearly the case here?

Mr. BECERRA. Congressman, first, I welcome the opportunity to get to know you and work with you, and thank you for the question and the thoughtful way in which you posed it.

I will tell you that we want to make sure that Americans have a choice. Lots of choice, right? But we want to make sure that, when they choose, they are getting something that has value. And so whatever the source, however it is put together, we just want to make sure that Americans have a choice of plans that offer real benefits.

Mr. CURTIS. I certainly can't disagree with that statement, but I do feel like sometimes that—those of us make value decisions for other people, and that sometimes we need to let them make their own informed decisions.

Now, let me just shift gears slightly. You have continually called for the ACA expansion while calling short-term plans "junk plans."

We have talked about that a number of times in this hearing. Despite this, the ACA plans have notoriously limited patient choices by cutting provider networks and implementing strict prior authorization standards, which only harm our most vulnerable patients.

Isn't this just another form of health discrimination?

And what would you say to rare disease patients with ACA plans who lost access to lifesaving care because of these actions?

Mr. BECERRA. Congressman, I bet you, if you and I sat down, we would find that we could agree on this issue because, at the end of the day, we are looking for comprehensive plans that have quality coverage for all Americans.

And there is, under the Affordable Care Act, a place for some short-term plans. But it is truly short-term plans for those who need short-term care, who are in between jobs, for example, or who are going overseas for a little while, and can't—don't have the luxury to have a plan that is long-term, because you only need it short-term. So there is a place for that.

But I think you and I would agree it is about quality, and making sure it is affordable for people. And the way you do that is to make sure that what they are getting is what they thought.

Mr. CURTIS. Well, let me be the first to invite you to Utah in your new role. We would love that conversation, and would love to have a thoughtful dialogue with you. And I can promise you a delightful experience out in Utah when your travels take you out that way.

Let me—speaking of Utah, I have a very, very large rural part of my district. About 80 percent of my geography is rural, but only about 10 or 15 percent of my constituents. Telehealth has played just an amazing, critical role during the pandemic. There is an increasing sense that, I will say, the train has left the station and these expanded services should be made permanent.

I am also aware that private insurers that have committed to permanently reimburse for telehealth services planned to that end.

What specific plans do you have for HHS related to telehealth, as States reopen again?

And what role do you see for Congress in making these plans permanent, especially for our seniors?

Mr. BECERRA. Congressman, I think just about everything you just said on telehealth I agree with. I would just—I would add a little bit.

We have learned a lot from COVID on how to do this. We want to make sure we offer flexibility, but we want to make sure that we don't leave anyone out. And so it is a matter of making sure that we understand that telehealth requires broadband. There are certain communities, especially rural communities, that don't have access to good broadband. It is going to take resources to make sure that happens. Some parts of the country already can use telehealth, but what we don't want to do is find the inequities that we found as a result of COVID, where we leave certain communities, rural or poor, behind.

And so we can do this working together, and it will take your effort, because some of these things we can do administratively, but a lot of it will——

Mr. CURTIS. I am going to run out of time, but I want to just tell you it is as if we teed each other up, because I wanted to talk broadband with you, and we just, hopefully—hopeful that you would support broadband as we reform it, and make it so it is more accessible.

And, Madam Chair, zero seconds left. I yield my time.

Ms. ESHOO. Good job, excellent job, Mr. Curtis. The gentleman yields back.

It is a pleasure to recognize our California colleague, Ms. Barragán, for her 5 minutes of questions.

Ms. BARRAGÁN. Thank you, Madam Chair, and thank you, Mr. Secretary, for joining us here today.

Just to chime in a little on the conversation about migrants at the border, I was just at the Donna facility last Friday. There has been remarkable progress with the almost 80 percent decline of kids that are now in Border Patrol custody. And that is why I want to applaud you, Mr. Secretary, for the work that you have done with HHS to get kids out of custody of Border Patrol as quickly as possible. When I was at the Donna facility, which, again, is a Border Patrol facility, there was no child there over 24 hours. So that has just been a success in the administration on their willingness to take action and to not have kids in Border Patrol custody.

I mean, I did visit some of the HHS facilities, one there at Delphi and, of course, the one in Long Beach, right next to my district—one, Mr. Secretary, I know you are visiting soon—to see that not only are children being tested before they arrive but they are being tested for COVID throughout the entire week there. And so it is great that you are able to visit that facility and see firsthand.

Mr. Secretary, I want to move on to a couple of issues that are near and dear to me. One is the issue of social determinants of health.

We saw, as a result of the COVID–19 pandemic, that communities of color were hit very hard. And we have also seen that—how a community's resources directly impact the health of its residents. Unsafe or unstable housing, food insecurity, the lack of transportation, all these things put some populations at higher risk during this pandemic emergency. Addressing these social determinants of health is crucial to reducing health disparities not only during the current crisis, but we must work to strengthen our public health infrastructure into the future.

I was excited to see that the President's budget request—$153 million to the CDC's Social Determinants of Health Program, which was modeled after my bill, the Improving Social Determinants of Health Act, or H.R. 379, which supports State, local, territorial, and Tribal health agencies—addresses these underlying issues that contribute to inequity.

Mr. Secretary, can you talk about the administration's commitment to addressing social determinants and why you believe funding programs, including at the CDC, is crucial in addressing disparities?

Mr. BECERRA. Congresswoman, thank you for the question, great to be with you, and I look forward to working with you on this particular issue. I know this is a lifetime commitment for you, as it is for me.

We are not only going to take the resources that the President wants to make available to us, but I have made it very clear throughout the Department, here at HHS, that equity will permeate everything we do. So it is not just in the programs that we are trying to administer or create, it is in everything that we will do at HHS. We take into account that we have to remember those who have oftentimes been left in the corners.

And so those social determinants of health, by the way, we need good data to know what those determinants are. We have to make sure we are collecting good data. We have to make sure we are working really hard with our local partners to make sure they also get it. That equity should be at the forefront of what they do.

And if you will give me a second, Congresswoman, I would like to just say thank you to you for your efforts and help in making sure that the Long Beach site that we are using for some of these unaccompanied migrant children is not only working, but working well. And I think I have to tip my hat to the people at the Health and Human Services agency who have been doing just a phenomenal job in making sure we do it the right way.

Ms. BARRAGÁN. Well, thank you. Thank you, Mr. Secretary.

I was excited to hear that the President discussed ending cancer as we know it during his joint address to Congress. I wish to take a moment to highlight one form of cancer, multiple myeloma. Unfortunately, my sister, who is only a year older than me, last November was diagnosed with multiple myeloma. It was pretty devastating for me and my family and, of course, to her and her family.

This is a cancer that forms—is a type of a blood cancer—let me back up here. Multiple myeloma is a cancer that forms in a type of white blood cell and accumulates in the bone marrow. In 2021 it is estimated that there will be 34,920 new cases of myeloma, and an estimated 12,410 people will die of this disease.

Unfortunately, large socioeconomic, geographic, and racial disparities exist in myeloma treatment, which can greatly impact patient outcomes. Among these disparities include delayed diagnosis, stem cell utilization rates, limited access to new therapies, and access to clinical trials.

I just wanted to put this on your radar, Mr. Secretary, so that we can make sure we are looking at things like multiple myeloma when we are looking at where to invest the $6.5 billion.

And I also want to applaud the administration and you for looking at climate change and making sure that we are looking at this as a public health crisis and addressing that, as well.

And with that, I yield back.

Ms. ESHOO. The gentlewoman's time has expired. It is a pleasure to recognize Dr. Joyce of Pennsylvania for his—am I doing this right? Yes.

Mr. JOYCE. Thank you.

Ms. ESHOO. Dr. Joyce, you are recognized for your 5 minutes.

Mr. JOYCE. Thank you, Chair Eshoo and Ranking Member.

This is a great opportunity to be with you here today, Secretary. I would like to return to some of the remarks that you made earlier, when it didn't seem clear that you understood what my colleague Mr. Bilirakis meant by the term "partial birth abortion."

And I think that it needs to be defined as it is in statute. Section 1531 of Title 18 U.S. Code is literally titled "Partial Birth Abortions Prohibited." That statute very clearly defines this inhumane procedure in section B, subsection 1.

So now, with that clarification, could you please recognize that that does exist in statute?

And I would ask you, do you agree that this law is correct?

Mr. BECERRA. Congressman, thank you very much, and thanks for trying to clarify. I actually—I think I understood the question, and I think I understand your question, as well. What I am trying to explain is that the term "partial birth abortion" may be recognized in politics and by politicians, but it is not a medically recognized term.

Perhaps, if you were to talk about what you probably know as dilation and extraction, which is a procedure used by OB/GYNs like my wife, to care for a woman who is having a difficult pregnancy, where there is a chance that the fetus will not survive, then we can talk about that.

But what I am saying to you is that, under the law, a physician or any provider of healthcare must make sure that it—he, or she, it abides by the law. And right now, what our law says, and it is pretty settled, is that a woman is entitled to reproductive rights.

And so my question is not so much with the term "partial birth abortion," it is with what the rights are of a woman under our statutes and under our precedents to provide her with reproductive care that she is entitled to. And, as my wife would tell you, as an OB–GYN, is that the dilation and extraction procedure that is often used, late-stage abortions for women, it is to protect the health and life of that woman.

Mr. JOYCE. So, just for further clarification, partial birth abortions are prohibited right now under current statute, and that is something that you recognize, correct, Mr. Secretary?

Mr. BECERRA. Congressman, as I said, I recognize that the law provides women with reproductive rights, and that the Roe versus Wade decision made very clear under what circumstances women can exercise those rights.

I will do everything I can to make sure we comply with precedent and the law when it comes to protecting a woman's right to her reproductive health.

Mr. JOYCE. And that does include enforcing this statute, correct?

Mr. BECERRA. I will make sure that we are providing women with the protections they need on their reproductive rights and, again, there—with all due respect, I know that this is a very sensitive issue for a lot of folks, but I think most medical practitioners will tell you they understand what a dilation and extraction procedure is. I doubt that most of them can give you a medical definition of what "partial birth abortion" is.

Mr. JOYCE. As a physician myself, Mr. Secretary, I think I clearly understand what a partial birth abortion is.

Let's move on at this point in time, please, and I see we are narrowing down.

During your tenure as the California attorney general, you sued the Federal Government to protect a California regulation that required churches to pay for abortions in their healthcare plans. You

also sued the Little Sisters of the Poor, seeking to force a Catholic group of nuns to pay for contraception and abortions.

During your confirmation hearing you stated that you would recuse yourself from participating in matters related to litigation you pursued against the Federal Government. Would you provide for us a list of every matter from which you would personally recuse yourself?

Mr. BECERRA. Congressman, first, to respond on to the actions that I took as the attorney general, again, as I said, I respect that there are different, deeply held beliefs on the matter of abortion. And what I did when I was attorney general was comply with the law and enforce the law.

But I will say to you, to correct the record, I never sued any nuns. I never sued any organization that had a religious exemption. What I did was I took actions to make sure that providers, who are under obligation by law to provide services to all people, including women who are pregnant, did so. And so, however it might be described, the reality is that I simply protected the rights of Americans to get the healthcare that they are entitled to under the law.

I have forgotten how the second part of that—or the second question that you had.

Mr. JOYCE. The second part asked you to include a list of any matters that you personally would recuse yourself because of previous litigation.

Mr. BECERRA. Yes, and I made it clear when I was getting confirmed that I signed an ethics agreement not to involve myself directly with any matters with which I was directly involved in litigation as attorney general for the State of California.

Ms. ESHOO. Right, and the gentleman's time has expired.

Mr. JOYCE. Thank you——

Ms. ESHOO. The Chair now—thank you. The Chair now recognizes the gentlewoman from Delaware, Ms. Lisa Blunt Rochester.

Ms. BLUNT ROCHESTER. Thank you so much, Madam Chairwoman and Ranking Member, and thank you, Secretary Becerra, for joining us and presenting the administration's fiscal year 2022 funding request for HHS.

As a former Delaware deputy secretary of health and social services, State personnel director, and CEO of our Urban League, I understand all too well the challenges you would face under normal times. But your leadership during this pandemic is critical, and we are so fortunate to have you in your role as we recover and rebuild.

I am also pleased to see our shared focus and priorities of strengthening outreach and enrollment in the ACA, a focus on the social determinants of health, telehealth, value-based healthcare systems, and systemic equity to improve outcomes. And I look forward to working with you.

Today I want to focus on an issue that has disproportionately affected communities of color: climate change. For decades, policy decisions at the Federal, State, and local levels have led Black, Brown and indigenous communities living near toxic and polluted environments, even though the link between these conditions—air pollution and increased rates of illness like cancer and asthma—is well documented.

The administration's funding request proposes establishing a new Office of Climate Change and Health Equity to reduce disparities in communities of color, low-wealth households, Tribal communities, and other marginalized groups overburdened by the health impacts of climate change.

Mr. Secretary, can you discuss how this office will differ from existing HHS agency efforts around climate change, such as the NIH climate change and human health, and the CDC climate and health programs?

Mr. BECERRA. Congresswoman, thank you for the question, and I absolutely appreciate the chance to respond to that. We are going to focus directly now, as a result of these resources, on climate change.

By the way, I should mention that, as attorney general, I established the Environmental Justice Bureau in our Department, because we know, as you have sort of said, it is our communities that are first and worst hit by climate change.

And so we want to get there before the hit gets there. And in order to do that, we have to have the resources to start letting people know about clean water, about asthma when you have dirty air, about those toxic sites that might be built in your community, about the impact of building a large warehouse right next to a school and residential communities, where you are going to have semi trucks driving 24/7, right by all those communities, spewing diesel gas—diesel exhaust.

And so we are going to get out there and work with communities to make sure we provide equity, but more importantly, we fight for—to protect the health of these communities.

Ms. BLUNT ROCHESTER. And how does this proposal build on past presidential initiatives to tackle the disproportionate impact of climate change?

Mr. BECERRA. Well, the most important way is it actually has money behind it. And that gives us a chance to really do something. You can always talk. You just have to have the resources and the fuel to walk. And we intend to walk our talk.

Ms. BLUNT ROCHESTER. Excellent. And my last question, I am going to kind of combine two. I want to talk a little bit about why the administration views it necessary to focus on health equity and also talk about what agencies or organizations will you seek to partner with through this office.

Mr. BECERRA. So COVID–19 exposed the worst parts of our system, where we miss people. I mean, they were hiding in plain sight, you and I know that. And now we see it. And so now we have an obligation to do something about it.

And I think what we will do differently is we are not going to just rely on the traditional sources of support. We are going to go directly to these communities that have been worst hit and first hit and ask them, "How can we help, because we know you have had to live this?"

And, for the first time, I think we can say we are going to bring some real resources behind what we want to do.

Ms. BLUNT ROCHESTER. Excellent, excellent. Thank you so much, Mr. Secretary. Again, we are looking forward to working with you on this issue as well as so many others. I was fortunate to work

to push for marketing and outreach in our More Health Education Act in the last Congress for the ACA, and I am so glad to see the efforts that the administration has made, especially during a pandemic, to ensure more people have access to healthcare. And I am looking forward to working with you on other issues as well.

Thank you, and Madam Chair, I yield back my time.

Ms. ESHOO. Excellent. The gentlewoman yields back. It is a pleasure to recognize our resident pharmacist on our committee, Mr. Secretary, the gentleman from Georgia, Mr. Carter, for 5 minutes.

Mr. CARTER. Thank you, Madam Chair. And thank you, Mr. Secretary, for being here.

Mr. Secretary, it has been almost 14 months now since the COVID–19 pandemic started. And it began in China, we know that. But we still don't know the origin, as far as whether it started at a wet market or if it started at the Institute of Virology. And we haven't even had an investigation into telling us this. And we need to get to the bottom of it, obviously. And I am sure you agree with that. We need to know so that we can prevent this from happening again. That is crucial.

I want to ask you very quickly, can you just give me your perspective on how the U.S. and the global community—because this, in fact, impacts all of us—how the global community can hold China accountable, and ensure that a credible investigation into the origin of the COVID–19 can be conducted?

Mr. BECERRA. Congressman, thank you for the question.

I agree with you, we want to make sure that there is a transparent process that is based on evidence, that helps guide us in trying to take a look at this and dig down deep. We want to have accountability. We are now back on stage with the World Health Organization, working with them. And we provided some guidance to them on what we think would make for a critical, thorough, comprehensive review of the circumstances behind COVID–19.

And so I look forward to partnering with you as we try to work with our international partners to make sure we get to the bottom of these things.

Mr. CARTER. Do you think that China and the World Health Organization should be pushed to allow an investigation into the possible origins, whether it be the wet market or the lab?

Mr. BECERRA. Well, we have already been pushing the WTO in trying to make sure that we do a thorough assessment of this. We have been in communication with China on any number of issues relating to COVID. And we are going to continue to push because, at the end of the day—I think you will agree with this—we have to understand how COVID surfaced, we have to understand how it spread, so we could try to make sure we are prepared for the next time we have this kind of a public health crisis.

Mr. CARTER. OK. Mr. Secretary, in 2017, this committee, the Energy and Commerce Committee, was instrumental in enactment of legislation that would allow consumers to have access to over-the-counter hearing aids. And it was bipartisan legislation, as is often the case out of this committee. I submit that this is the most bipartisan committee in Congress.

And on the bipartisan basis, the House and the Senate repeatedly inquired of the FDA on the status of this regulation. But ever since last year, month after month, the FDA just says, "It is a priority, but we can't tell you where the regulation is at."

I am hearing—and I have been told—that there are rumors that the regulation can't move until we have a permanent FDA Commissioner. Is that true?

Mr. BECERRA. First, that is not true. And secondly, if I can just say that my mom doesn't live in Georgia, but if she did she would vote for you right now, because she is one of those victims of these hearing aid marketing schemes and is anxious to hear my answer, just as you are.

And so I look forward to working with you, because we are going to get that out. We don't have to wait until we have a permanent Commissioner. It is an important rulemaking, and we will work closely with you on trying to make sure that Americans, if they are going to participate in purchasing these hearing aids, they get what they are supposed to get.

Mr. CARTER. Do you have a date, a date certain, that you can tell me?

I mean, is it——

Mr. BECERRA. Congressman, if I could tell you a date certain, I probably would have to give folks a date certain on a lot of other matters. We are working on it. But I can tell you—my mom is probably going to push harder than you are on getting a date certain——

Mr. CARTER. I understand. Is it still undergoing [audio malfunction].

Mr. BECERRA. It is still undergoing review——

Mr. CARTER. Any idea when that will be completed?

Mr. BECERRA [continuing]. On that, Congressman.

Mr. CARTER. Please [audio malfunction] suffer from antimicrobial—infections, and we have over 48,000—infections, and we have seen, with the COVID–19 pandemic, as it continues, a sizable number of patients are suffering from secondary infections, with CDC identifying resistant secondary infections, outbreaks as COVID–19—this reinforces, in my opinion, the urgent need to—for access to effective antimicrobial products as part of our pandemic preparedness and response.

Can you commit to me, Mr. Secretary, that—working together to address the antimicrobial resistance in a way that creates [audio malfunction].

Mr. BECERRA. [Audio malfunction] deadly afraid of what happens if we overuse some of these [audio malfunction]. So absolutely, I look forward to working with you on that.

Mr. CARTER. We also need to——

Ms. ESHOO. The gentleman's——

Mr. CARTER [continuing]. Work with the overprescribing of certain antibiotics, as well.

Ms. ESHOO. The gentleman's time——

Mr. CARTER. As a pharmacist, I can tell you that is a problem.

Thank you, Madam Chair and I yield.

Ms. ESHOO. Yes, the gentleman's time has expired.

The Chair is pleased to recognize the gentlewoman from Minnesota——

Ms. CRAIG. Well, thank you so much——

Ms. ESHOO [continuing]. Ms. Craig, for your 5 minutes.

Ms. CRAIG [continuing]. Madam Chairwoman, and Mr. Secretary, it is great to see you again. The last time I saw you in person, I was in—we were in Eagan, Minnesota. So it is great to see you.

I want to start just by saying thank you. I can't tell you how pleased I am about yesterday's announcement that HHS will enforce civil rights protections for LGBTQ Americans related to healthcare. So thank you so much for your leadership, and the administration's inclusion as a matter of policy.

Also, as I listen to your testimony here today, it is all of the reasons and thinking behind why I am here. That is, we have got to have a robust funding program for the NIH, for CDC, restocking the national stockpile, addressing maternal mortality and morbidity. All of these things is exactly why it is such an honor to serve on the Health Subcommittee in this Congress. And I am just so proud of your leadership in this administration.

Beyond all of that, in the funding for these agencies and making sure that we have world-class innovation coming out of them, my top priority in Congress is to lower the cost of healthcare and prescription drugs and improve access for all Americans.

Last month I was proud to reintroduce a bill called the State Health Care Premium Reduction Act that would provide HHS with funding to help States set up reinsurance programs or extend financial assistance to folks on the individual market. We all know that that remains a critical issue, lowering and stabilizing the cost of healthcare out there in the individual market. According to the CBO, this bill would actually lower premiums by about 8 percent in the individual market.

Secretary Becerra, do you have any comments on that, as a policy matter, and does HHS support, just as we did for a few years at the beginning of the Affordable Care Act, helping States with Federal funding to set up those reinsurance programs and lower premiums in the individual market?

Mr. BECERRA. Congresswoman, great to see you, and I absolutely agree with what you have said. We need to have a stable market. Reinsurance is one of the ways that we can help make sure we do.

Ms. CRAIG. Well, thank you so much for that. Reinsurance, obviously, is just one tool, I know, that we can use to shore up the ACA and to make sure that healthcare is more affordable for hardworking Minnesota families.

Next I want to turn to the American Rescue Plan just—for just a moment, which included health insurance premium assistance for so many Americans at a time when they are struggling financially. And I want to give credit to my colleague and classmate, Representative Lauren Underwood, for her championing and persistence in making sure that this was part of the American Rescue Plan.

The landmark legislation extended ACA subsidies to more Americans, including, for the first time, individuals with income above 400 percent of the Federal poverty line.

I also just want to take a moment to give this administration credit for reopening, for that Special Enrollment Period during a public health crisis, the ACA to Americans.

So, Secretary Becerra, can you just briefly discuss the impact of the enhanced subsidies on premiums and how many individuals you have seen already with their monthly premiums decrease?

Mr. BECERRA. Congresswoman, the fact that there are a million new enrollees to the Affordable Care Act during the Special Enrollment Period shows what happens when you give them a chance to learn that they can save money. And that was because of what you all did with the American Recovery Plan, by giving us a chance to reduce the cost of their premiums.

Now, the American Family Plan, which we hope that you will get to as well, will make permanent those savings that those Americans who are signing up for coverage are getting. And I—what is great is, if you get 4 million more Americans coming on board because they too will save money, that is what you have done. You have just put a major—and to the chairman's thinking—more than just a dent in the uninsured in America, you are really going towards getting us to the point where every American can really say healthcare is a right, not just a privilege.

Ms. CRAIG. Secretary Becerra, you read my mind, because that was my last question to you about making that permanent. So thank you so much.

In the time that I have remaining, I just want to note that—the importance of the 340B program, how important that is for providing access to care for low-income and rural patients in my district. I would encourage you to take swift action to protect that vital program.

And with that, Madam Chairwoman, I yield back.

Ms. ESHOO. The gentlewoman yields back. It is a pleasure to recognize the gentleman from Texas, Mr. Crenshaw.

And it is great to have you with us. You are recognized.

Mr. CRENSHAW. Thank you, Madam Chair. It is always great to be with you, as well. I wish I could be with all of you in DC. But, you know, I guess there is a small benefit of this surgery. You can't go to DC for 6 weeks. But I do miss you guys.

Mr. Secretary, thank you for being with us. I want to follow up on Dr. Burgess' questioning on the situation with Texas and our 1115 waiver, and I want to drill down as to why this happened.

So this is a longstanding waiver, the extension of which was rejected by a career staffer at CMS who was temporarily the head of CMS. It doesn't seem likely that they just took it upon themselves to reject that waiver. Who told them to do that?

Mr. BECERRA. Congressman, I wish you well in getting back to DC, although I imagine you are not missing not being in DC and getting to stay in your home State.

But on the question of the waiver, again, I think it is important to recognize that Texas still has its waiver. Its waiver continues in force. Nothing has changed. What we are talking about is an extension of 10 years that was added to the existing waiver without public comment and without notice. And that was—that is extraordinary, when you think about it, given that it was a 10-year waiv-

er, not a 5-year or shorter waiver. And it—you are talking about billions of dollars.

And so what CMS is doing is what we would expect CMS to do, is we are trying to make sure that we are transparent and we show accountability, because we have to make sure we are following the law, and we are working with your leadership in the State and along with your delegation to try to make sure that, as Texas moves forward, if it wants to continue the waiver, we are going to be working with you to make sure we can see that happen.

Mr. CRENSHAW. OK, so it had your full approval to revoke that waiver that was approved by the previous—or revoke that extension that was approved by the previous administration and had the White House's approval, your approval? It wasn't some staffer that went rogue.

Mr. BECERRA. Well, I can guarantee you that there is not a staffer that is going rogue. But remember, much of the work that was done was done before I was confirmed.

But what I will tell you is I concur with the actions that were taken by CMS in looking closely and working with Texas to look closely at the waiver that they have asked for as an extension. Again, the existing——

Mr. CRENSHAW. Well, we understand there might be disagreements on the interpretation of the powers under COVID, right? They approved it in a fast-track way under COVID. That is what happened. Your administration disagrees with that interpretation. So be it.

But to revoke an entire waiver, which has a massive effect for the future of Texas programs, I mean, it puts us into a very difficult situation because our entire system is predicated on this particular waiver, and it is a longstanding waiver too. You know, it is—yes, it is an extension of a longstanding waiver. This isn't some extreme thing. What is extreme is revoking an extension, which has never been done before.

So, you know, if you have a procedural issue with it, I get that. But to take such an extreme action as a result is really hard for Texans to understand. And can you commit right now that, if they resubmit, that it will get approved?

Mr. BECERRA. Well, we are closely working with Texas to make sure, if they wish to resubmit, they can.

But Congressman, I would have to say that any time you are talking about getting an extension 2 years in advance and using COVID as the reason why you had to do it without giving Americans a chance to know about it or to comment, that is, to me, is a stretch.

All I know is that we have to abide by the law at HHS and at CMS. We have to be transparent in the way we do it. All we are asking is that Texas participate with us to make sure that that transparency is there.

Mr. CRENSHAW. OK, so they applied for it under the letter of the law. If they resubmit, can you guarantee that it will be approved if they submit it according to the law, as they already did?

Mr. BECERRA. If and when Texas resubmits, we will look at that, according to the law, and we will go through the process that provides for notice and comment, so we can make sure that we get the

input of all stakeholders to make sure that whatever Texas does complies with the law and has the support of those who are going to be impacted.

Mr. CRENSHAW. My last question. You seemed to indicate earlier that you actually do not support or do not recognize the statute on partial birth abortions. Can we answer that more clearly now?

Yes or no, do you recognize the statute that outlaws partial birth abortions?

Mr. BECERRA. So, again, trying to be as clear as I can on this. There are procedures that are used in providing women with the healthcare they need, including when they have——

Mr. CRENSHAW. It is a very clear statute, Mr. Secretary, please don't waver on this. The Supreme Court has already spoken on this particular statute. Do you recognize it, yes or no?

Mr. BECERRA. Well, I certainly recognize what the Supreme Court has said. And we will abide by what the Supreme Court requires, and we are going to make sure that we protect women's rights to healthcare.

Ms. ESHOO. The gentleman's time has expired. We thank him——

Mr. CRENSHAW. Thank you.

Ms. ESHOO [continuing]. For his questions. And heal and be well.

The Chair is now pleased to recognize——

Mr. CRENSHAW. Thank you, I yield back.

Ms. ESHOO [continuing]. One of the fine doctors on our subcommittee, Dr. Schrier of Washington State, for 5 minutes.

Ms. SCHRIER. Thank you so much, Madam Chair, and welcome, Secretary Becerra. Thank you for coming to this committee to talk with us about your priorities in the HHS budget.

First, just as a pediatrician, I want to thank you for prioritizing children in so many ways. But I want to talk about something else today. I want to the Advanced Research Projects Agency for Health, ARPA–H, to focus on breakthrough research for diseases like cancer, diabetes, and Alzheimer's. We have just witnessed, with Operation Warp Speed, how quickly medical advances can happen when government targets investment and ameliorates that risk. And this keeps us right on the cutting edge of research and development to treat and cure some of our most devastating and dreaded diseases.

Now, I was also especially thrilled to see the investment in the Office of the Assistant Secretary for Preparedness and Response, in ASPR, and I agree that defeating COVID–19 should be our current priority, along with preparedness for the next public health challenge or pandemic. This one has been quite a lesson in preparedness and in what we can even do better next time.

And I would also suggest that readiness to quickly deploy a robust testing strategy, in addition to shoring up our national stockpile, is critical for this pandemic and for the next one.

And depending on how effective the current vaccines remain—right now things are looking good—and also, depending on how many of us get vaccinated, testing might be able to take a back seat for right now, but that is a big may. And we have all seen how important rapid diagnostics are in containing disease and containing the spread.

And we didn't do it well in the U.S. We really stumbled at first, we never really caught up. We are still not doing surveillance testing. Even today—and the vaccines are proven to be remarkably effective, but suboptimal public uptake and global circulation means that we are probably going to be living with COVID–19 for a long time. And I just want to make sure that we are using every tool we have. We still need to have a robust testing program for diagnosis and surveillance that includes inexpensive at-home tests that could be manufactured at scale, and we need it now, thinking about schools, and we will need it for future infectious disease threats.

And the coordinated interagency work of the CDC, the Department of Defense, NIH, FDA, and ASPR is doing to reopen schools and get that testing to market is phenomenal. I want to highlight the work that ASPR has done with BARDA. However, even in their own assessment, they acknowledge that testing still needs to be more widely available, more affordable, and more convenient.

So, Secretary Becerra, can you just tell us if you have plans for additional investments in ASPR, BARDA to continue developing and deploying a really sustainable and scalable testing strategy?

Mr. BECERRA. Congresswoman, thank you for the question. And listen, I can't agree more with what you have just said, and we discussed—I answered some questions about testing a little earlier.

We are not done. Even if we fully vaccinate, we are not done. We have a lot of work to do because testing, it is the prevention part of dealing with an illness or a crisis. It is trying to avoid it from spreading and becoming the pandemic, the real crisis. And testing will be part of any package that we try to implement to make sure that we are dealing with healthcare crises moving forward.

By the way, I would be remiss if I didn't thank you for the work that you have made in—done in helping us ensure that we have testing available for Americans throughout the country, and perhaps it is because of your own background and training that you understand that, in order to keep people healthy, especially our kids, we want to make sure that we know where the crisis might occur.

And so we are going to continue to make investments. ASPR is critical. BARDA is critical. ARPA–H will be just innovative and breakthrough in helping us get there. So I hope we can work with you to make sure that testing is part of any program that we have to protect Americans.

Ms. SCHRIER. I would love that. And I know there was a question earlier about what are we going to do with all this extra money for testing. I can think of a million ways to spend it, and one of them is having tests that cost—right now, $12 each is our over-the-counter test, and that is just too much for using on a regular basis. So I could see investing boldly there. I could see deploying testing in elementary schools until we have vaccinations roll out and widely accepted for kids.

Last question. You talked about Congress helping. Is there anything that you specifically need from Congress to make surveillance, home testing, scaling up possible?

Mr. BECERRA. Aside from the resources, I would tell you your connections. You know the people on the ground in your district

who can help us most. Help us connect with them as quickly as possible.

Ms. SCHRIER. OK, great. Thank you.

Ms. ESHOO. The gentlewoman's time has expired. It is a pleasure to recognize the gentlewoman from Arizona.

Mrs. Lesko, you have 5 minutes.

Mrs. LESKO. Thank you very much, Madam Chair. Before I get to my question I would like to ask unanimous consent to submit a copy of an article from ABC 15 News in Phoenix for the record. It is entitled "Valley Family Pleads with FDA for Access to Experimental Drug for Fatal Children's Disease."

Ms. ESHOO [AUDIO MALFUNCTION]. Need to submit it.

Mrs. LESKO. Thank you.

Secretary Becerra, thank you for being here. The FDA's world-class drug [audio malfunction].

Ms. ESHOO. Am I unmuted?

Mrs. Lesko, you need to unmute. Can you hear us?

Mr. GUTHRIE. I think she is frozen.

Mrs. LESKO. Yes.

Mr. GUTHRIE. There she is.

Ms. ESHOO. There you are.

Mrs. LESKO. I am unmuted on my side.

Ms. ESHOO. All right, start your question again, because we didn't hear it.

Mr. GUTHRIE. Madam Chair, I think she is freezing up.

Ms. ESHOO. Yes, why don't we——

Mrs. LESKO. All right. Can you hear me now?

Mr. GUTHRIE. Yes.

Ms. ESHOO. Yes, go ahead.

Mrs. LESKO. All right, I am just going to use—I think what is happening is I have my statement, and I am just going to read it.

Secretary Becerra, thank you for being here. The FDA's world-class drug approval process ensures medicines do exponentially more good than harm to the American public. But in rare situations, the only option for very ill people is a medicine that is not yet approved by the FDA. These are dealt with under the FDA's compassionate use or extended use program.

I want to bring to your attention, sir, Woodrow Miller. He is a constituent of mine who is only 21 months old and, tragically, has Niemann-Pick Type C disease. NPC is a rare, progressive genetic disorder which can begin to show symptoms in children very early in their lives. Symptoms include difficulty moving limbs, an enlarged spleen or liver, a decline in intellect, dementia, seizures, difficulty speaking and swallowing, a loss of muscular functioning, loss of vision or hearing. The one glimmer of happiness in this very tragic prognosis is the medicine that doctors in the field of neurology believe can delay, for some children, the most impactful symptoms of the disease.

Unfortunately, due to a discontinued clinical trial, Woodrow is not able to gain access to the medicine his doctor believes can help him. I have spoken to Woodrow's mother, Denise, and I want to do everything I can to help. Denise has spoken with many doctors. We have got letters from many doctors and heard Woodrow's doctor. My staff has also spoken with Denise and have been in touch with

the FDA staff, both through the phone and email. FDA staff are sympathetic and responsive but have not found a path forward yet.

Last week I sent a letter to Acting Commissioner Woodcock, asking her to review Woodrow's situation and use the authorities at her disposal to help Woodrow quickly gain access to the medicine his doctor recommends. Quite frankly, time is of the essence. I can't stress this enough. NPC is a degenerative disease. Once the child loses functions, it is unlikely he will regain them.

Mr. Secretary, will you direct your staff to follow up on the status of FDA's response to my request to help Woodrow gain access to the medicine his doctors believe can help him?

And will you emphasize they should use all appropriate options?

Thank you, sir.

Mr. BECERRA. Congresswoman, first, thank you very much for pointing out what so many Americans, unfortunately, suffer, and that is the plight of loved ones with these very rare diseases. I am absolutely willing to make sure that I follow up with your request with Acting Commissioner Woodcock.

And what I will tell you is what I said to the folks at the FDR recently—FDA, excuse me, FDA recently—and that is that I recognize their independence. They base their actions on science, not on politics and influence. And so I will absolutely communicate your message. I suspect that she is—she and her team are working on it, as well, and understand the heartfelt way that you have conveyed that message. And we will try to get back to you quickly as we can.

Mrs. LESKO. Thank you, Mr. Secretary. I appreciate it. My constituent appreciates it. Anything you could do would be greatly appreciated.

And I yield back, Madam Chair.

Ms. ESHOO. The gentlewoman yields back.

It is a pleasure to recognize the gentlewoman from Massachusetts, Mrs. Trahan, for your 5 minutes of questions.

And I want to thank members for staying on time, because it looks like we are going to be able to accommodate everyone, including Mr. Doyle.

So you are recognized for 5 minutes.

Mrs. TRAHAN. Thank you, Madam Chair.

Hi, Mr. Secretary, thank you so much for being here with us today. Your appointment has sent a clear signal that the Department will once again prioritize expanding affordable, accessible, high-quality healthcare for all Americans, including those in our underserved communities.

In my district, no one has done more to deliver that quality, affordable care to the underserved, and under extremely challenging circumstances, than the nurses and doctors and administrators at Lawrence General Hospital in Lawrence, Massachusetts. They serve the 80,000 residents of a beautiful, bustling, diverse, and historic city on the banks of the Merrimack River, the force that powered America's Industrial Revolution.

Eighty percent of the city's residents is Latino, and you may remember that the area was sparked by a series of natural gas explosions back in September of 2018.

You know, just as the city was recovering, the pandemic struck, setting progress back. On a per capita basis, the city has suffered greater numbers of COVID infections than any of our 350 cities and towns in Massachusetts. And at one point, three-quarters of Lawrence General's in-patient capacity was dedicated to recovering COVID–19 patients.

Time and again, Lawrence General has come through for the community, particularly the 20 percent living in poverty. Indeed, approximately 75 percent of its patient population is public payer, primarily Medicare and Medicaid.

You know, last month I wrote to you, along with Senators Warren and Markey, asking the Department to give Lawrence General the highest possible consideration for aid—of Provider Relief Funds. And your congressional team has been extremely responsive and helpful. But I wanted to personally alert you to this issue, given the incredible strain that the pandemic has put on the hospital. The assistance that Lawrence General has received thus far has been instrumental in allowing the hospital to continue operating despite higher costs and lower revenues. However, even with that assistance, the hospital is in a fragile financial position. And I can only imagine this is the case for many safety net hospitals serving similar populations across the country.

So, Mr. Secretary, given that the Federal relief to the Nation's hospitals thus far has significantly helped these facilities to serve on the front lines of the pandemic, does the Department plan on relieving hospitals of financial burdens even further through enhanced PRF relief or advanced Medicare payments or any other measures?

Mr. BECERRA. Congresswoman, first, thank you for the question.

But secondly, thank you for the work that you have done on behalf of Lawrence General. We have learned a lot from Lawrence General. And I will tell you that Lawrence General and those safety net hospitals that were on the front lines deserve our attention.

And when it comes to that Provider Relief Fund, it was meant—you all passed that so we could actually address the needs of those providers that stepped up to the plate. And so what I can tell you is that, having represented, when I was in Congress, a number of those safety net hospitals myself, how important it is that we not let them fall through the cracks because they are the ones that were there before we had the pandemic, serving these populations that were very vulnerable.

And so I could only commit to you that, under my leadership, I hope that you will see that HHS is trying to do right by all those who stepped up to the plate, those safety net providers, and that we are doing the right thing with the Provider Relief Fund. That is why accountability and transparency will be so important as we disperse those final tranches of dollars.

Mrs. TRAHAN. Well, I appreciate your thoughtful answer.

On the topic of provider relief, I also just wanted to raise concern regarding equity of distribution of the Provider Relief Fund. Assisted living providers—elderly individuals—less than 2 percent of the Provider Relief Fund, and have only received about a third of that. You know, due to PPE needs, workforce needs, occupancy declines, assisted living caregivers suffer—losses in 2020 alone. Now,

over half of assisted living facilities nationwide are operating at a loss, and 56 percent say they won't be able to sustain operations for another year. I recently signed a bipartisan letter asking HHS for a more equitable distribution of the remaining PRF to assisted living facilities.

So, Mr. Secretary, how do you envision implementing an equitable distribution to these assisted living providers who need immediate assistance?

Mr. BECERRA. Congresswoman, that is a great question, and there is where the transparency that we will ensure is going to be, I hope, our best response there, because there is more need than there is money. And what we have to do is prove to you and others that, when we disperse those funds, it is based on real need, that we can be accountable for the dollars that we send out.

And so I offer you the chance to continue to work with my team and me, as we try to make sure we do right with those Provider Relief Funds.

Mrs. TRAHAN. Well, thank you so much, Mr. Secretary. And I—please consider this an open invitation to come to the Merrimack Valley to meet the wonderful professionals at Lawrence General some time soon.

I thank you, Madam Chair. I yield back.

Ms. ESHOO. The gentlewoman yields back.

It is a pleasure to recognize Mrs. Fletcher from Texas for your 5 minutes of questions.

Mrs. FLETCHER. Thank you so much——

Ms. ESHOO. Great to see you, Lizzie.

Mrs. FLETCHER [continuing]. Chairwoman Eshoo.

And Secretary Becerra, thank you for sharing your priorities with us today, and your thoughts on the priorities of those on this committee. Unlike so many of my colleagues that I have heard earlier today, I arrived in Congress after you had returned to California to serve as attorney general. So I am glad to meet you today this way and very much look forward to working with you.

You are taking the reins of HHS at a critical moment in our history. And there is so much work to be done as we emerge from this pandemic, and many issues that we have been working to address since before it began. And I want to take my time today to talk about an issue of critical importance in my district in Houston and across the country: the Title X Family Planning Program.

I have become fond of reminding people that Title X—which is the only Federal program dedicated to family planning and which provides critical preventive healthcare services for millions of low-income Americans each year—Title X was born in Texas 7. It was introduced in Congress by my predecessor in this seat, then-Congressman George H.W. Bush. This program has long had bipartisan support across our community, and it plays a vital role in ensuring access to essential services.

Unfortunately, the last administration's actions to impose an ideological domestic gag rule meant that millions lost access to care under this program, as thousands of health insurers were forced out of the program. Six States have gone more than a year without any Title X-funded health centers. In 2019, 800,000 fewer patients

received care under Title X as compared to 2018, and in 2020 the reduction was even greater.

So I am pleased that the administration's budget request enhances the funding for Title X after years of flat funding so we can restore Title X to its true purpose intended by Congress: to provide preventive healthcare and family planning services to those who need it the most.

I am interested in better understanding the administration's timeline for implementing changes to the Title X program and when we can expect the quality family planning providers that were shut out of the program under the last administration to be able to once again serve patients.

Secretary Becerra, can you discuss the administration's request for additional Title X funding and why this increase in funding is so critical?

Mr. BECERRA. I absolutely can, Congresswoman, and I look forward to the opportunity to get to know you better and develop the friendships I have with many of the Members that you sit with.

Listen, Title X is crucial. It is family planning. It is preparing our families for a bright future for their kids and them. It is making sure that we do the right thing. And we have to make sure that services are available. It is not just for women. Obviously mostly women, but it is not just for women. And you may know I did a lot of work when I was attorney general to protect Title X and its services, and we are going to fight just as hard.

Thank you for what you did to make sure that there was $50 million made available through the ARP so we could make sure family planning services were made available.

We are going to do everything we can to restore some of those services. The President's budget increases funding for Title X. It is just the right thing to do. I mean, it is—we can't be about families first if we are not providing them with the services they need to make the right decisions about moving forward with their family.

And so I will tell you that, working with those of you who are interested, we are going to launch as best we can, as quickly as we can, but we have to make sure we do it right. If we are going to promulgate rules, we have to do it the right way. And we are going to make sure that we do this right, so we can service the people who need those family planning services.

Mrs. FLETCHER. Great. Well, thank you so much for that. And, I guess, one quick follow-up. I would love to work with you on this and would love to know if you can tell us any more now about how you intend to restore the program to ensure that more patients are served.

Mr. BECERRA. Again, when we get closer to promulgating those rules, we will be able to work together. But I don't want to get too far ahead of ourselves because, as I said, we have to make sure we do this the right way.

Mrs. FLETCHER. OK, well, thank you for that. I appreciate your efforts. Title X is a critical aspect of our healthcare safety net, and millions of patients rely on access to care through this program each year. So I encourage you to address it quickly and look forward to working with you on that and to restoring the program.

And with the time I have left, I do want to just touch on an issue that my colleagues from Texas have raised about the administration's withdrawal of its approval of Texas' 1115 waiver extension.

As you likely know, Texas is in a healthcare crisis. It has the highest uninsured rate in the country. It is certainly my hope that Texas will expand Medicaid, especially considering the incentives in the American Rescue Plan that we worked on in this committee. Now—but I hope we can work together to address the concerns that have been raised. It is clear that, even if Texas were to expand Medicaid, there would still be a need for some form of 1115 waiver to fund any existing uncompensated care in the State. And, of course, we hope it will be done in a transparent way and in a way that provides quality care to disadvantaged Texans.

So I am glad to hear that you are working closely with people in Texas now, and I urge you to work with them to accomplish these vitally important objectives to our State. So thank you so much, Secretary Becerra.

And with that I will yield back.

Ms. ESHOO. The gentlewoman yields back. I don't see Mr. Schrader, so I am going to go to Mr. Doyle, who is waiving on, and he has been with us since the beginning of the hearing today.

So you are recognized, my friend, for 5 minutes.

Mr. DOYLE. Well, I want to thank the chair, and my good friend, for allowing me to waive on to the committee.

Mr. Secretary, congratulations to my friend and former colleague, Xavier. It is good to see you. It has been too many years, but good to have you back and in this very, very important position.

I want to start out with an issue that is a matter of urgency for Pennsylvania and our Medicaid program. On January 8th, the Trump administration put out a regulation around Medicaid managed care contracts that is going to force Pennsylvania to completely redo formulas for how our Medicaid program reimburses hospitals and nursing homes in 2022. This regulation reversed about a decade's worth of approvals for the way Pennsylvania pays our managed care providers. And while CMS believes Pennsylvania can transition to alternative directed payments, our Governor, our secretary of health, our hospital association, and I are all concerned that this does not fully account for the difficulties, risks, and implications of such an abrupt policy change.

In fact, the real timeline only provides our State a few weeks to develop the needed policy changes, since they also need actuarial approval prior to the end of the year. Unfortunately, this scramble puts Medicaid payments to hospitals and nursing homes at risk during a pandemic, which I hope we can all agree is counter to our shared goals.

Ultimately, this change could force hospitals and nursing facilities to limit Medicaid beneficiary access if they are faced with funding uncertainty, which does not seem to be in line with President Biden's larger efforts on healthcare. We understand CMS has concerns around current policies. And although we don't completely agree with those concerns, we really believe more time is needed to discuss this and develop a path forward that works for both sides.

So my question is, Mr. Secretary, will you commit to working with us on this issue and consider delaying this new guidance for a year?

Mr. BECERRA. Congressman, good to see you, and thank you for the question. I know this is of importance to you, because I have had several conversations now with Governor Wolf on this particular subject, and we will continue to have those conversations. Our team is now chatting more directly with your folks back in Pennsylvania. You have my commitment that we are going to work—try to work through this.

It is a complicated issue, and I can't even describe it all, because I have to have my folks at CMS sit down with me a little bit more, because in my first conversation with Governor Wolf I was hoping we would be able to get back to him really quickly, because I know that time is of the essence.

But what I could commit to you is that we are going to be sitting down with Governor Wolf and his team and, if you would like, your staff as well, to make sure we work through this as best possible.

Mr. DOYLE. I appreciate that, and it is really important to us.

Let me just ask you one more question too. It is a bit broader question, but something I am also excited to work with you on.

I am sure you know the rates of antibiotic resistance have been on the rise for some time, and yet we still aren't seeing an active pipeline of new drugs to fight these resistant infections. So my question is, what resources does HHS plan to dedicate to the development of new antibiotics and antimicrobials in the coming year?

And has HHS considered shifting the way we pay for antibiotics to ensure a steady stream of new drugs?

Mr. BECERRA. Congressman, it is going to be an all-of-the-above approach, because I think everyone is recognizing that we are beginning to lose those defenses against some of these very deadly diseases if we don't tackle this quickly. So we are willing to listen to whatever anyone has to offer.

We certainly will take resources as well, because we do want to develop the next generation of antimicrobials so we can be ready. And so we will be ready on that.

Mr. DOYLE. Well, thank you very much, Mr. Secretary. It is good to see you back here in Washington.

Madam Chair, I will yield back a minute to you, and thank you for your courtesy.

Mr. BECERRA. And Madam Chair——

Ms. ESHOO. Thank you. Yes, thank you, Mr. Doyle.

Mr. Secretary, let me ask you a quick question.

Mr. BECERRA. Yes.

Ms. ESHOO. We have about, I think, 4 minutes left, but we have two Members that will bring their questions to you in a rapid manner. They have waived on to the committee. Can you stay with us just to accommodate the two?

Mr. BECERRA. It is hard for me to tell friends and colleagues no. So let me—if we can do this quickly, I will stick around.

Ms. ESHOO. That was the right answer. That was terrific, music to my ears.

All right, so we will go to Mr. McNerney of California for his 5 minutes.

And if you can question faster than that, that would be terrific. You are recognized.

Mr. MCNERNEY. Well, thank you, Chairwoman Eshoo.

And thank you, Secretary Becerra, it is great to see you. I think you are doing a great job this afternoon here.

I appreciate the administration acknowledges the clear link between climate change and human health. The scientific community has been warning us for years about the consequences of climate change. What I wanted to do was expand upon Congresswoman Blunt Rochester's questions.

The administration is requesting funding level increases for the NIH Climate Change and Human Health Program and the CDC Climate and Health Program. These initiatives fund research on the health impacts of climate change and adapt our public responses accordingly.

The previous administration intentionally silenced the scientific community's concerns about climate change. How will you reverse the negative impacts of the prior administration's policies?

Mr. BECERRA. Congressman, great to see you, and of course I would get a scientific question from a scientist. I will say to you that we are—the fact that we are establishing, at the direction of the President, this office that will deal directly with climate change is a clear message of our commitment to deal with climate change as a healthcare—public health issue.

And, you know, my work as AG in California, where we took on this issue, established the Bureau of Environmental Justice, we understand that those who are worst and first hit are usually those vulnerable communities. So we are going to tackle this one because we have no choice if we truly want to have Americans stay healthy,

Mr. MCNERNEY. Well, how—will increasing the budget for climate and health effects at NIH and CDC strengthen public health departments and labs in the response to climate change?

Mr. BECERRA. Without a doubt. And we will take whatever resources you can give us because, you know, there is not enough that we have right now.

Mr. MCNERNEY. Well, we know that climate change affects everyone, but it has disproportionate impacts on low-income and minority communities. For your perspective, how will investing in the NIH and CDC programs reduce these disparities?

Mr. BECERRA. You know, as much as California fights to have clean air, if you live—if you have a child in the Central Valley, there is a one in four chance that your child will have asthma. Why? Because of the air, the air quality. And so we have to do everything we can, working with our local partners, working with Congress, to make sure we are addressing this.

Congressman McNerney, on this one you have me, I will try to do everything we can.

Mr. MCNERNEY. Very good. And, as you are aware, you just mentioned the Central Valley in California suffers from some of the worst air quality in the country. This has been made significantly worse by the wildfires. In fact, the New York Times article by Dr. Kari Nadeau suggested that the exposure to wildfire smoke is associated with genetic changes in children's immune cells. This is very disturbing.

How can the HHS work with the DoE and the EPA to mitigate and prevent harm like this?

Mr. BECERRA. We each have jurisdiction, we each have responsibilities, and we each have reach to make a difference. And hopefully, coordinating, we can make a difference faster and further than if we try to do it all by ourselves.

Mr. MCNERNEY. That is great. I look forward to working with you, Secretary, and this is the big issue that affects all of us, but especially in the Central Valley.

Thank you, I yield back.

Ms. ESHOO. The gentleman yields back, and I thank him for yielding back the extra time.

And last but not least, the Chair recognizes the gentleman—and that is what he is—from New York.

Mr. Tonko, you are recognized for questioning.

Mr. TONKO. Thank you, Madam Chair——

Ms. ESHOO. I didn't want to say 5 minutes, though, because the Secretary has to run, so——

Mr. TONKO. OK.

Ms. ESHOO [continuing]. As quickly as you possibly——

Mr. TONKO. Thank you, Madam Chair, for your—and thank you, Secretary Becerra. Congratulations, and thank you for your leadership in joining us today.

I applaud the Department of Health and Human Services with their important step in moving forward with new buprenorphine practice guidelines that will save lives. But I am concerned, though, that the X waiver itself remains, which means prescribers will have to actively apply for what, essentially, will be a waiver to the waiver. This will leave an unnecessary barrier in place. Secretary, I appreciate your previous comments, that the X waiver requirement should be removed, and we look forward to working with you to accomplish this important goal.

So my question is, was HHS limited in its actions it could take regarding fully implementing the X waiver and lifting patient caps?

Mr. BECERRA. Congressman, you know this better than anyone, you have worked on it harder than anyone, and you know the answer to that is yes, we were constrained.

Mr. TONKO. So I have—I would like, Madam Chair, to enter for the record a letter supporting urgency in passage of the bipartisan Mainstreaming Addiction Treatment Act. It is signed by some 120 organizations.

And as you know, I am a proud supporter of the MAT Act, which would fully eliminate the X waiver requirement and authorize the Secretary of HHS to conduct a national campaign to educate practitioners about the change in law and encourage providers to integrate evidence-based medication-assisted treatment into their practices.

So would HHS support congressional action to authorize the Secretary of HHS to conduct a national campaign to do this education and encourage providers to integrate evidence-based medication-assisted treatment into their practices?

Mr. BECERRA. Congressman, it is crucial that we expand access. And so what I can tell you is we will absolutely be supportive of any congressional action to help us expand access. How you do it,

I am no longer there, I no longer have a vote. I wish you well as you try to move this forward. I know you have been a champion on this issue. But please, help us have expanded access.

Mr. TONKO. Thank you, thank you.

My other issue is the Medicaid reentry, which would empower States to restore Medicaid eligibility for incarcerated individuals up to 30 days before their release to ensure that those transitioning will have immediate access to critical services, including mental health support, addiction treatment, and COVID testing. Granting the States this ability is a great way to respond to their quality of life and to destroy the statistics out there, which have too many people vulnerable to addiction as they are released.

Is the President still committed to this population, and would he be willing to include this provision in his budget?

Mr. BECERRA. Congressman, you know the President has been talking about expanding access to healthcare to all. You know he has said it should be a right, not a privilege. And as we move forward with restorative justice to help those who have moved on in life, we certainly would have to make sure we are including them. So I can't—I won't speak directly for him, but I can tell you the commitment of this administration is to make sure everyone has access to quality, affordable healthcare.

Mr. TONKO. Well, we—thank you. And I just hope you can consider talking to OMB about including the Medicaid reentry in your budget.

And with that, you know, I thank you, Madam Chair, for your flexibility.

And, Mr. Secretary, congratulations on your appointment, and I look forward to working with you.

Ms. ESHOO. The gentleman yields——

Mr. TONKO. I yield back.

Ms. ESHOO. The gentleman yields back, and we want to thank the Secretary for his flexibility in accommodating those that just waived on.

Mr. Secretary, thank you for a very full part of the day in joining us. We look forward to many other hearings and, very importantly, the day-to-day work with Members from the subcommittee, and others as well.

Anyone that tuned into this had a front-row seat of how much work has been done on the good-news front relative to COVID but how much more work we have to do on behalf of the American people. And, you know, as a former Member of the House, there is nothing that kind of raises the ire of Members than not getting a direct answer to a direct question.

So, you know, pursuant to the committee rules, Members have 10 days to submit their additional questions for the record. I will do that, and ask you to respond as—in a really timely fashion, but get to the answer so that we can move down the road of making progress.

So we wish you godspeed with this massive portfolio that you have.

Everything that we do, and the words that are embedded in the statutes, in the legislation, those are all words that walk into peoples' lives. And we know—we have confidence that you understand

that and have a great regard for it, having been one of the shapers of the words and legislation. Now you are an implementer.

So we want to give the best language—put the best language forward, but we will, obviously, work very hard with you to make sure that there is implementation. So godspeed and thank you.

I thank all the members of the subcommittee, those that waived on, and at this—oh, let me ask the wonderful ranking member.

We have 18 documents to submit for the record. And I would like to request—I have a unanimous consent request that these documents, including Mrs. Lesko's, be placed in the record.

Mr. GUTHRIE. There is no objection.

[The information appears at the conclusion of the hearing.]

Ms. ESHOO. Thank you, Mr. Guthrie. I appreciate that. You are always such a gentleman, a pleasure to work with.

So at this time the subcommittee is adjourned.

[Whereupon, at 2:08 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Congress of the United States
Washington, DC 20515

May 11, 2021

Honorable Xavier Becerra
Secretary, Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Dear Secretary Becerra:

Congratulations on your recent confirmation to serve as the Secretary of Health and Human Services. We look forward to working together in your new role to ensure the Medicare program continues to provide high-quality, affordable care. For over two decades, Medicare Advantage (MA) has been integral to fulfilling the Medicare guarantee, offering choices, affordability, and meeting the holistic health needs of seniors and those with disabilities, today providing coverage to 42 percent of all Medicare beneficiaries totaling over 26 million seniors.[1]

Collectively, we represent districts where the majority – over 50 percent, and in some cases over 60 percent – of seniors chose to enroll in MA. There are 90 Congressional Districts like ours, as well as the United States' most populous territory, Puerto Rico, that represent more than 7.2 million seniors enrolled in the program.[2] In our districts the majority of seniors are enrolled in the program. We write to express our strong bipartisan support for MA and encourage you to protect and strengthen this important choice for seniors in the Medicare program. MA is delivering high-quality, affordable coverage, and is uniquely positioned to ensure seniors receive the care and support they need during the pandemic and beyond while improving health outcomes and advancing health equity for over 26 million seniors.

MA serves a diverse population, 28 percent of beneficiaries are racial and ethnic minorities, as compared to 21 percent in Medicare-Fee-for-Service (FFS). Currently, 55 percent of Latino and 39 percent of African American beneficiaries have actively chosen to enroll in MA and there is growing diversity in enrollment because of the value provided to beneficiaries.[3] Furthermore, more than half of MA beneficiaries have low-fixed incomes of less than $30,000 annually, underscoring the critical need for access to affordable health care coverage.[4] MA provides financial protections from high out-of-pocket costs not available in Medicare FFS, which is particularly important for approximately 50 percent of seniors enrolled in MA whose incomes fall below 200% of the Federal Poverty Level.[5] A recent analysis found that beneficiaries in MA are spending nearly $1,600 less annually out-of-pocket compared to beneficiaries in Medicare (FFS).[6]

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[1] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData
[2] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn
[3] https://www.ahip.org/wp-content/uploads/MA_Demographics_Report_2019.pdf
[4] https://www.ahip.org/wp-content/uploads/MA_Demographics_Report_2019.pdf
[5] https://bettermedicarealliance.org/wp-content/uploads/2020/04/BMA-FactsSheet.low_modestincomes-003.pdf
[6] https://bettermedicarealliance.org/wp-content/uploads/2020/04/BMA-FactsSheet.low_modestincomes-003.pdf

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Nearly all MA beneficiaries report satisfaction with their health coverage in part because it is focused on diagnosing and treating chronic conditions early to minimize disease progression, avoiding hospitalization, and coordinating care.[7] MA provides innovative and affordable benefits designed to address social determinants of health that are not available in Medicare FFS including transportation to providers, nutrition services and meal delivery, post-acute care coordination services, dental, vision, hearing, and other wellness benefits.

MA's additional benefits and services are demonstrating results and improving health outcomes. Recent research shows that compared to Medicare FFS, MA beneficiaries are 20 percent more likely to have an annual preventive care visit and have a 52 percent lower rate of complications for beneficiaries with diabetes.[8] [9] Importantly, MA beneficiaries spend less time in the hospital – beneficiaries with chronic conditions experienced 23 percent fewer inpatient hospital stays and 33 percent fewer emergency room visits than similar individuals in Medicare FFS.[10]

In response to the COVID-19 pandemic, MA took swift action to protect and support seniors and those with disabilities, including delivering meals, providing personal protective equipment, activating clinical outreach, and enhancing touchpoints with providers through telehealth to keep beneficiaries healthy. MA plans also helped launch a pilot program called Vaccine Community Connectors in March. The program aims to quickly vaccinate seniors through vaccine education, appointment scheduling, transportation services, and partnering with federal, state, and local officials to deliver vaccines to underserved communities. Additionally, crucial financial protections were provided to seniors including waiving co-pays for primary care, telehealth, and COVID-19 medical treatment.

Again, congratulations on your confirmation. We look forward to working with you to protect and strengthen MA for the over 26 million seniors it serves, including the millions of seniors we collectively represent across our Congressional Districts who rely on this critical Medicare program to deliver high-quality, affordable health care that is improving health outcomes and advancing health equity across the country.

Sincerely,

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[7] https://bettermedicarealliance.org/wp-content/uploads/2021/01/BMA_Seniors-on-Medicare-Memo_.pdf

[8] Sukyung Chung, Lenard I. Lesser, Diane S. Lauderdale, Nicole E. Johns, Latha P. Palaniappan and Harold S. Luft. Medicare Annual Preventive Care Visits: Use Increased Among Fee-For-Service Patients, But Many Do Not Participate. Health Affairs, 34, no.1 (2015):11-20.

[9] Avalere. "Medicare Advantage Achieves Cost-Effective Care and Better Outcomes for Beneficiaries with Chronic Conditions Relative to Fee-for-Service Medicare." Published July 2018. http://avalere.com/expertise/managed-care/insights/medicare-advantage-achieves-better-health-outcomes-and-lower-utilization-of.

[10] Avalere. "Medicare Advantage Achieves Cost-Effective Care and Better Outcomes for Beneficiaries with Chronic Conditions Relative to Fee-for-Service Medicare." Published July 2018. http://avalere.com/expertise/managed-care/insights/medicare-advantage-achieves-better-health-outcomes-and-lower-utilization-of.

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Cc: House Speaker Nancy Pelosi
House Minority Leader Kevin McCarthy
Senate Majority Leader Chuck Schumer
Senate Minority Leader Mitch McConnell

Texas Hospital Association

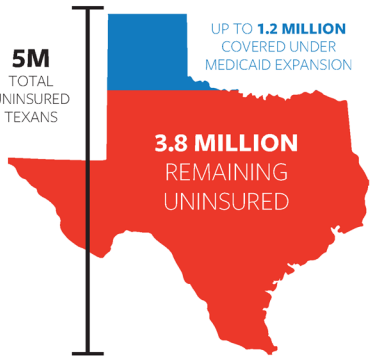
Losing Texas' Waiver Extension Destabilizes the Health Care Safety Net

The Centers for Medicare & Medicaid Services on April 16 rescinded the 10-year extension of Texas' Medicaid 1115 Waiver that the previous administration approved in January. While CMS stated that it rescinded Texas' waiver extension because it had not complied with certain emergency public notice requirements, some view the waiver rescission as a path to force Medicaid expansion in Texas. Hospitals disagree with this approach and clarify that:

1. **The waiver extension and Medicaid expansion are not mutually exclusive.**
2. **Loss of the waiver extension will have devastating consequences for Texas' health care safety net and patients' access to care.**

While current waiver's uncompensated care pool and managed care authority remain in effect through Sept. 30, 2022, the rescission jeopardizes about **$32 billion in new funding and about $10 billion in additional available federal financial support.** This funding, amid the ongoing pandemic, is essential to transition the Delivery System Reform Incentive Payment program and stabilize the health care safety for the millions of Texans who rely upon it each day.

The Waiver and Coverage Expansion Should Work Together



The uncompensated care pool is the foundation on which health care services for the uninsured are delivered in Texas. Coverage expansion alone cannot meet the needs of Texas' entire uninsured population. Hospitals support coverage expansion and drawing down the federal dollars available. **However, only about**

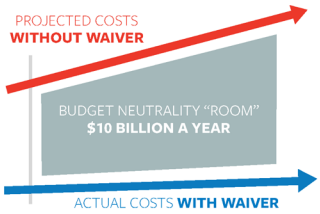
ONE IN FIVE UNINSURED TEXANS

would be covered if the state expanded Medicaid eligibility. The remainder would not qualify for Medicaid and still will seek care often at hospitals, where federal law requires hospitals to provide emergency care to those seeking it, regardless of their ability to pay. A strong UC pool is needed on an ongoing basis to help offset some of the cost providers will continue to incur for delivering unreimbursed care to Texans without health insurance.

Loss of the Waiver Extension Hinders Access to Care

Millions of vulnerable Texans rely on the health care safety net. From routine health care services to chronic disease management to behavioral health and public health support to specialized, life-saving care, the waiver extension would have supported critical infrastructure in communities across the state. The loss of Texas' waiver extension cannot be understated.

Budget Certainty. The extension preserved about $10 billion in access to federal funding known as budget neutrality "room," or savings generated under the existing waiver that otherwise would have been lost had HHSC pursued a new waiver instead of an extension. Preserving the existing budget neutrality room gave the state certainty in the amount it could spend going forward to expand existing supplemental payment programs and develop new directed payment programs.



Loss of the waiver extension now puts Texas back in danger of facing a budget neutrality "cliff." Under budget neutrality, states cannot spend more with a waiver than they would without one. Based on CMS guidance, the savings Texas has generated by spending under its federal budget neutrality cap can be carried forward continuously in an existing waiver but would be lost under a new waiver. If the state pursues a new waiver, it likely will lose the $10 billion in budget neutrality room associated with the current waiver. This funding loss hinders the state's ability to ensure a stable health care safety net and access to timely care for millions of Texans.

New UC Pool. A wide range of health care providers, beyond Texas hospitals, provide care for the uninsured. Local public health providers and community mental health centers would have received about $5 billion over the life of the extension through a new UC pool to offset uncompensated care costs for providing behavioral health services, immunizations, chronic disease prevention and other preventive and public health services.

DSRIP Transition. While DSRIP was a success, CMS was clear that it would not be renewed. *DSRIP funding ends Sept. 30, 2021.* Texas developed several new directed payment programs that would build DSRIP successes and learnings into Medicaid managed care. Without the waiver extension, the state does not have the funding to transition DSRIP.

Directed Payment Programs. In addition to helping transition DSRIP, HHSC was working with CMS for approval of several new DPPs, set to begin Oct. 1, 2021, to help stabilize the health care safety net through the pandemic and beyond. Expenditure authority for and program size of the DPPs was tied in part to the budget neutrality room afforded under the extension. The extension would have carried forward existing funds and allowed new spending to improve care quality and patients' access to services.

- **Comprehensive Hospital Increased Reimbursement Program: $5 billion for hospitals annually**
- **Texas Incentives for Physicians and Professional Services: $600 million for physician group practices annually**
- **Rural Access to Primary and Preventive Services: $19 million for rural health clinics annually**
- **Ambulance Average Commercial Reimbursement: $150 million ambulance providers annually**
- **Behavioral Health Services: $166 million for community mental health centers annually**

Next Steps

Texas hospitals are working with the state to determine the ongoing impact of the waiver rescission and identify next steps. Hospitals will continue to support a coverage expansion option for low wage working Texans. However, a UC pool and a safety net program that pay providers closer to the cost of providing care will also continue to be a necessity. Funding for the necessary existing UC pool and the state's managed care authority expire Sept. 30, 2022. It is now unclear how, whether or when the UC pool will be continued or sized. HHSC will need to negotiate a new waiver to continue UC funding and Medicaid managed care, which can take months or even years. Conversely, the state potentially could revert to the former Upper Payment Limit methodology to help offset some of providers' UC costs should the state opt to not seek a new waiver or continue Medicaid managed care. Regardless of the decision, hospitals are committed to providing the best quality care to all patients and encourages a thoughtful discussion to ensure the needs of Texas' growing population will be met.

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FOR IMMEDIATE RELEASE
April 19, 2021

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PRESS RELEASE

Texas Council of Community Centers Expresses Deep Concerns About Impact of Federal Government's Reversal of the 10-Year 1115 Waiver Extension

(AUSTIN, Texas – April 19, 2021) – The following is a statement from Danette Castle, CEO of the Texas Council of Community Centers regarding the impact of the federal government's action to rescind the 10-year Medicaid 1115 waiver extension, agreed upon after months of negotiation between the State of Texas and the federal government.

"The Texas Council of Community Centers expresses deep concerns about the federal government's abrupt termination of the 10-year 1115 Medicaid Waiver Extension. Because of this action, the public mental health system will lose more than $300 million a year in federal funding with disastrous consequences for more than 250,000 people with serious mental illness and substance addictions who currently rely on services funded by this program. Now slated to end on September 30, 2021, and with no replacement strategy in place, the Delivery System Reform Incentive Payment (DSRIP) program, which funds these life-saving services, has enabled the public mental health system to virtually eliminate waiting lists for mental health treatment and take important steps to improve care by advancing statewide implementation of Certified Community Behavioral Health Clinics, a service delivery model promoted by the Centers for Medicare and Medicaid Services (CMS) as an innovative treatment model. The Texas Council of Community Centers urges the federal government to take necessary and immediate steps to sustain critical healthcare funding for public safety net providers in Texas by approving the State's previously submitted request to continue the DSRIP program at current funding level or authorizing an alternate financing strategy until a longer-term solution can be approved and implemented."

About the Texas Council:
As an association, the Texas Council of Community Centers represents the statutorily authorized Community Mental Health and Intellectual Disability Centers of Texas that manage, develop and provide community based services to Texans with mental illness, intellectual disabilities and substance addictions across all 254 counties of Texas.

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Texas Council of Community Centers, Westpark Building 3, Suite 240
8140 N. Mopac Expressway Austin, Texas 78759
www.txcouncil.com

The Washington Post
Democracy Dies in Darkness

White House is split over how to vaccinate the world

A proposal to waive drugmakers' patents to enable developing countries to make generic vaccines wins some backers in the Biden administration

By Dan Diamond and Jeff Stein

April 30, 2021 at 2:57 p.m. EDT

A high-stakes fight over drug companies' response to the coronavirus pandemic has split the Biden administration, with activists and progressives urging the White House to back an international petition to waive the companies' patents — and some senior officials privately signaling they're open to the idea.

The debate has reignited decades-old tensions in global health, pitting such influential figures as Pope Francis, who backs the patent-waiver proposal, against philanthropist Bill Gates, who's opposed. It has also challenged U.S. officials who have prioritized this nation's coronavirus response but know that the virus's continued spread and mutation overseas will eventually pose risks to Americans.

The proposal was discussed last week by Anthony S. Fauci, a top coronavirus adviser to President Biden, and Katherine Tai, the U.S. trade representative, who spoke about ways to help the developing world as it reels from a worsening crisis.

Fauci briefed Tai on the benefits of sharing technologies from companies that hold vaccine patents — a position that he supports, arguing that it would allow developing countries to rapidly produce their own vaccines, said people with knowledge of White House deliberations who spoke on the condition of anonymity because of the conversations' sensitivity. Tai separately told colleagues that she's considered advocating to lift some patent protections but is still gathering information, said two of those people.

But other officials in the Commerce Department and the coronavirus task force warn that waiving the patents could backfire, including by handing intellectual property to international rivals. They also say that allowing new manufacturers to compete for scarce vaccine ingredients and expertise could hinder existing production, and that donating doses to countries in need would be more efficient.

The patent fight centers on a proposal in front of the World Trade Organization, which would allow the global trade body's 164 member nations to stop enforcing a group of coronavirus-related patents for the duration of the pandemic.

That proposal has been spearheaded by India and South Africa, which argue that relaxing the patents would allow more countries to produce or import generic versions of coronavirus vaccines, rather than wait months or years for enough doses to immunize their populations. Dozens of developing countries have signed on to the seven-month-old effort, which has attracted renewed attention as the virus ravages India, causing thousands of deaths per day and the rationing of health services.

But the United States and other wealthy nations, including Britain and Canada, have helped block the petition, with officials worried that it would throw global vaccine production into disarray, prompting advocates to complain that the White House is prioritizing drug companies' billion-dollar profits rather than the billions of people still waiting for their first shots.

"We're putting a lot of pressure on the Biden administration because the U.S. public actually co-funded a lot of this research through Operation Warp Speed," said Fatima Hassan, who leads South Africa's Health Justice Initiative and is among the activists calling for a "people's vaccine."

Hassan said the companies have treated the vaccines as a "commodity" rather than a public good, and she appealed to Biden to pressure the companies to voluntarily share their scientific discoveries — or face the temporary loss of their patents. "It's really amazing to me that you have one of the most powerful countries in the world, and it can't take on four CEOs," Hassan added, charging that the leaders of Moderna, Johnson & Johnson, Pfizer and AstraZeneca have not done enough to make their coronavirus vaccines available to developing countries.

Pharmaceutical companies counter that they've taken dramatic steps to aid the global response, such as collaborating on vaccine development to produce as many as 10 billion doses this year, with more than 1.5 billion of those reserved for poorer countries. Industry officials say accelerating vaccine production would provide more rapid assistance to hard-hit nations.

"We could hand them the patents, and we could say, 'These are the types of quality-control measures that have to be in place.' But you know, it can take us five to 10 years to stand up a brand-new manufacturing facility," said Anne McDonald Pritchett, a senior vice president at the Pharmaceutical Research and Manufacturers of America, the industry's trade association.

The drug industry, along with other businesses and outside intellectual-property experts, also has warned the White House that loosening the patents would create a thicket of legal challenges and could backfire when the pandemic is over. For instance, rival nations such as China and Russia are eager to learn the secrets of the technology behind vaccines supported by billions of dollars in U.S. taxpayer funds.

Waiving the patent protections would be "disastrous for innovation. It would be very bad for the United States in the long term and short term," argued Andrei Iancu, who was undersecretary of commerce for intellectual property and director of the U.S. Patent and Trademark Office during the Trump administration.

Inside the White House, officials have wrestled with how to proceed, with some teams pushing to use the patent issue as leverage with the pharmaceutical industry to ramp up its global efforts and others worried that it would subvert the United States' own coronavirus response.

Indian Prime Minister Narendra Modi raised the patent issue in a call Monday with Biden, according to a statement from Modi's office. White House officials declined to comment on the conversation and the administration's broader deliberations. While Biden did not directly address the issue in his speech to Congress on Wednesday night, he vowed that the United States "will become an arsenal of vaccines for other countries, just as America was the arsenal of democracy for the world." Officials are debating how many millions of stockpiled doses to donate.

The patent fight has intensified as public health experts warn that the coronavirus pandemic is worsening in India and other parts of the world, even as it recedes in the United States. The World Health Organization reported 5.7 million new global cases last week, an 8 percent weekly jump and the highest level on record, driven by the explosion of infections in India.

"In light of this growing humanitarian crisis, I urge you to leverage all tools and resources available to the United States to provide relief to India," Sen. Elizabeth Warren (D-Mass.) wrote Biden on Wednesday, laying out possible steps such as using the waiver to compel companies to share their "know-how" with the World Health Organization.

'We have ... an artificial scarcity'

For some global health experts, the coronavirus fight has fueled an old accusation: that wealthy nations and deep-pocketed companies are hoarding expertise and treatments, while less-fortunate nations wait and suffer.

It's also evoked comparisons to a 1990s-era battle that pitted drugmakers with patented HIV medicines against health officials in developing countries trying to manufacture cheaper generics. That fight culminated in former South African president Nelson Mandela accusing the companies of using patents to try to profit off the spreading outbreak in his country, prompting drugmakers to back down.

The renewed tensions have spilled out in public, including in a briefing Wednesday by the ONE Campaign, a global health advocacy organization.

"It's a very divisive issue, let's be honest about this," said José Manuel Barroso, a former prime minister of Portugal and chair of a global vaccine alliance known as Gavi, which is backed by pharmaceutical companies. Barroso said that in his personal capacity, he had supported the temporary waiver of vaccine patents. "But frankly, now [in] 2021, this will not solve our problem," he added, calling instead for more sharing and production of doses that he argued would lead to quicker results.

"I respectfully disagree," countered Winnie Byanyima, the executive director of the Joint United Nations Program on HIV/AIDS, which is part of a pro-waiver coalition. "Just a handful of companies actually can decide who gets the vaccine, who gets to buy and who gets to be vaccinated. Yes, we can talk about donations but surely cannot donate what is not there — we have a scarcity. And it's an artificial scarcity."

While the White House has touted its decision to share millions of doses and supplies with India this week, advocates also say it puts a spotlight on what Biden didn't do. "This piecemeal response and using exceptional measures and charity to respond to a situation of a grave public health crisis is not a sustainable way to move forward," said Hassan, the South African advocate.

Hassan also noted that under South Africa's plan, vaccines will not be widely available until late 2021 and she may not be immunized until February 2022. "I'm under 65, I have no comorbidities, so I'll rightly be last in line," she said.

About 0.5 percent of South Africans and 9 percent of Indians have been vaccinated against the coronavirus so far, compared with more than 43 percent of Americans, according to data tracked by the Our World in Data project at the University of Oxford.

White House divisions

Within the Biden administration, the patent-protection debate has split the White House along multiple political and policy factions, said three officials with knowledge of the discussions. Progressives have argued with centrists about

whether the administration is wrongly siding with the pharmaceutical industry, which has lobbied to preserve its patent protections. International aid experts have wrangled with the officials focused on domestic virus response, who have worried that efforts to shake up global supply chains could undercut efforts to help Americans now.

"The people whose job it is to protect the property of U.S. businesses are up in arms that it's a bad idea," said one official involved in the patent discussions who spoke on the condition of anonymity. "The people whose job is to defeat the pandemic are much more receptive to it."

[Perspective | Waiving vaccine patents won't help inoculate poorer nations]

The growing pressure over patent protections has emerged as an early test for Tai, the new U.S. trade representative, who is expected to soon make a recommendation to the White House about whether to support waiving some of the requirements overseen by the World Trade Organization's Council for Trade-Related Aspects of Intellectual Property Rights, or TRIPS.

Tai told a World Trade Organization virtual conference this month that "the highest standards of courage and sacrifice are demanded of us in times of crisis. The same needs to be demanded of industry" — a comment widely interpreted as a signal that drugmakers should brace for a waiver recommendation.

But officials familiar with Tai's thinking said the trade representative was committed to hearing all sides, noting that she held conversations this week with leaders of companies that hold patents on vaccines as well as with experts like Gates. Tai also is exploring whether there might be ways to boost global vaccine production without waiving the requirements altogether, such as by having WTO member nations use emergency powers to produce patent-protected products.

Some of the health officials who helped develop the coronavirus vaccines being deployed across the United States have argued that more can be done to speed vaccine production. Barney Graham, deputy director at the Vaccine Research Center at the National Institutes of Health, said the U.S. government has "some leverage," having developed some of the technology used in Moderna's vaccine.

"I think everyone is in agreement that working as fast as we can to provide vaccines for the world is in the best interests of everyone since we are all in this together, and the faster we vaccinate, the less likely new variants will emerge," Graham said.

'A wake-up call'

Drug industry leaders share that assessment but contend that they've taken appropriate steps to vaccinate the world, pointing to arrangements with Covax, an initiative set up to distribute billions of coronavirus vaccines globally. The administration's priority, they say, should be to help source supplies to make the vaccines, which can have hundreds of proprietary components.

"One of our biggest challenges is, simply, the access to some of the critical raw materials that we need," said PhRMA's McDonald Pritchett, noting that phospholipids, one key ingredient in the mRNA vaccines, are produced by just four manufacturers, including one that is attempting to ramp up its production about 100-fold since last year. "We need to identify additional ways to further expand capacity."

Progressives' rallying cry is that the crisis is a test of the nation's moral authority in the world.

"The Biden administration has an obligation to reverse the damage done by the Trump administration and reestablish our nation's global reputation as a public health leader," Rep. Rosa L. DeLauro (D-Conn.), chair of the House Appropriations Committee, said last month, calling for the waiver.

But other lawmakers who oppose the waiver warn that loosening the protections would harm the nation on the global stage. Sen. Christopher A. Coons (D-Del.), a close ally of Biden, has even invoked the Jan. 6 storming of the Capitol among the reasons to protect patents, saying it revealed the need to unite the country.

"All of this is a wake-up call for us that we need to have another Sputnik-like moment of reinvestment in American innovation and competitiveness," Coons added at a think tank event last week. "A central part of being successful in this competition is continuing with our constitutionally created protected-property right of a patent."

By Dan Diamond

Dan Diamond is a national health reporter for The Washington Post. He joined The Post in 2021 after five years at Politico, where he covered the Trump administration and the coronavirus pandemic. Twitter

By Jeff Stein

Jeff Stein is the White House economics reporter for The Washington Post. He was a crime reporter for the Syracuse Post-Standard and, in 2014, founded the local news nonprofit the Ithaca Voice in Upstate New York. He was also a reporter for Vox. Twitter

The Washington Post
Democracy Dies in Darkness

Opinion: A patent-free 'people's vaccine' is not the best way to help poor countries

Opinion by the Editorial Board
May 3, 2021 at 4:43 p.m. EDT

THE WORSENING global pandemic, with the virus surging not only in India but also in Brazil, Turkey, Iran, Argentina and elsewhere, has stirred outrage over the lack of vaccines in the developing world. Rich countries are inoculating millions of people, while poor countries wait in agony and anxiety. This has given fresh impetus to demands that patent protection be temporarily stripped from vaccines to deliver everyone a free "people's vaccine."

The goal is noble, but the demand is more slogan than solution. What the world needs are political leaders prepared to make hard, emergency decisions to stop viral transmission, such as immediate lockdowns, and renewed leadership from the United States and other rich nations to help accelerate global vaccine production and sharing, which will save lives later. Better than the chimera of a "people's vaccine" are doses of vaccines that are proven safe and efficacious against the virus and capable of protecting against the growing list of variants.

This week, renewed attention is focused on an effort spearheaded by India and South Africa, and supported by more than 50 nations as well as nongovernmental organizations and a large group of Democrats in Congress, to waive World Trade Organization protections on intellectual property in hopes of disseminating vaccine technology more widely. At issue are protections covering copyrights, industrial designs, patents and trade secrets. The Post's Dan Diamond and Jeff Stein report the Biden administration is divided over the idea, and the new U.S. trade representative, Katherine Tai, is studying it in advance of WTO meetings this week.

It is true that pharmaceutical companies stand to profit handsomely from monopolies on individual patented vaccines. It is also true that stripping away their intellectual property now could discourage future innovation. The U.S. government spent some $10 billion in Operation Warp Speed to help that effort, among other things, but did not require companies to turn over their intellectual property to the government — or to share it.

The most salient fact is that patents on vaccines are not the central bottleneck, and even if turned over to other nations, would not quickly result in more shots. This is because vaccine manufacturing is exacting and time-consuming. Look at the production difficulties encountered by Emergent BioSolutions, a vaccine manufacturer in Baltimore, where 15 million doses were contaminated. That was caught before the shots were distributed, but one can imagine the horrific consequences of a failure to maintain quality control elsewhere in the world.

Far more useful than stripping the patents would be a concerted U.S. effort to share manufacturing know-how, experienced personnel, quality control methods, oversight and raw materials. The U.S. manufacturers should be encouraged to strike licensing deals, too, in order to speed production in qualified facilities elsewhere. The United States also should share its sizable vaccine surplus with the world, beyond those doses already pledged to Canada and

Mexico. The Covax Facility for poorer nations, now crimped by supply interruptions from India, urgently needs 20 million doses in the next few months. This is how rich countries can really help the poorer ones.

Read more:

Madhukar Pai and Manu Prakash: India's covid-19 crisis is a dire warning for all countries

Joseph E. Stiglitz and Lori Wallach: Preserving intellectual property barriers to covid-19 vaccines is morally wrong and foolish

Ashish K. Jha: India's coronavirus surge could collapse its health system. The U.S. can help.

Josh Rogin: The United States can't ignore China's vaccine diplomacy in Latin America

Christine Emba: Everyone is tired. We need to give ourselves an actual break.

Updated April 19, 2021

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Vaccines: J&J vaccine pause | Tracker by state | Guidance for vaccinated people | How long does immunity last? | County-level vaccine data

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Biotechnology Innovation Organization

Dr Michelle McMurry-Heath
President & CEO

May 3, 2021

The Honorable Joseph R. Biden
President
The White House
Washington, DC

Dear Mr. President,

The worsening COVID crises in India, Brazil and elsewhere has intensified the need for all interested global parties – governments, industry, multilateral organizations and non-profit organizations -- to urgently step-up efforts to get COVID vaccines and therapeutics to the patients who need them most, wherever in the world they may live.

In the past year, over 950 research and development projects to address COVID have been launched, 70% of them by small and medium sized companies. These efforts can only truly be successful if they result in patients around the world receiving safe, effective treatments and vaccines. Clearly further action is needed if we are to achieve true global social justice in addressing the COVID crisis. The United States is poised, with existing and soon-to-be-expanded capacity, to truly the be world's "arsenal of vaccines" as you called for last week.

With this goal in mind, we at BIO would like to suggest the establishment of a **COVID Global Strategy for Harnessing Access Reaching Everyone (SHARE) Program,** to be implemented immediately. The Global SHARE Program would consist of three parts: 1) Ensuring sufficient global *supply* of vaccines; 2) Ensuring safe and expeditious global *access* to vaccines and therapeutics; and, 3) Ongoing Efforts to strengthen and support healthcare systems in low-and middle-income countries in addressing COVID.

We propose the following policies and actions be taken:

1) <u>Ensuring Sufficient Global Supply</u>

- To facilitate optimal production of safe and effective vaccines globally, governments, with the support of the WTO, need to *adopt policies that facilitate and expedite the export of key raw materials* and manufacturing supplies needed for COVID-19 vaccine manufacturing. This will help speed the delivery of doses produced by ALL manufacturers worldwide.
- Governments, working with industry, *urgently need to identify key bottlenecks in the global supply chain* for vaccines, and determine how to most quickly but safely facilitate the development of new supply where necessary. A global mechanism for tracking the supply chain, managed by an independent third party, will soon be announced. This initiative should help ensure timely and accurate data on product shortages and supplies and should be strongly supported by the US government.
- *COVID vaccine manufacturers need to continue to make all practicable efforts to increase their output in a safe and effective manner*, by putting in new capacity and by engaging in voluntary licenses with partners who are capable of meeting regulatory GMP standards. BIO is pleased acknowledge for example the recent announcement of

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Moderna to increase its production of vaccines to 3 billion doses next year. Current projections show that global manufacturing capacity continues to grow and should reach or exceed 10 billion doses before the end of 2021.

- The United States government should work with its allies to further *strengthen the global supply chain by encouraging and coordinating investments in global suppliers* of raw materials and consumables. Efforts can be undertaken to add suppliers of key materials in the short and long term to best support the increased level of vaccine manufacturing capacity around the world.

2) Ensuring Safe and Expeditious Global Access to Vaccines

- The United States government, and other governments with significant domestic vaccine supplies, should *pledge to donate a meaningful proportion of these supplies to low- and middle-income countries* through COVAX or other effective means.

- The United States should work with U.S.-based manufacturers *to allow export of COVID-19 vaccines from American facilities*. Many vaccine manufacturers have significantly increased their U.S. capacity and this could be used to urgently supply doses to both COVAX and countries with bi-lateral arrangements with companies. The United States is now poised to be, as President Biden declared "the arsenal of vaccines" for world.

- *COVID manufacturers* should likewise, through COVAX or other direct means, put in place and announce concrete plans to *commit and ship significant quantities of vaccines to low- and middle-income countries*. In some cases, this will require legal permissions by governments to allow for the export of finished vaccine doses.

- The United States should demonstrate global leadership with other high-income countries and multilateral organizations by *urgently donating resources to low-and middle-income healthcare systems to ensure that vaccines can be distributed and provided safely and effectively* to needy populations.

- *Low-and middle-income countries should adopt policies to accept and adopt regulatory approvals in countries of origin* with stringent regulatory agencies (e.g., FDA, EMA, MHRA), and forgo putting in place additional regulatory hurdles in place that would slow access to vaccines.

- The U.S. government should provide *aid to the COVAX countries seeking to implement the WHO's No-Fault Compensation program* and continue to invest funds to strengthen national pharmaco-vigilance and surveillance programs. These continued investments will help protect patients and providers, provide essential information about SARS-Cov-2 variants and vaccine efficacy, and build vital infrastructure for future pandemics.

- Vaccines and other products procured by COVAX or by individual nations for donation to low-and middle-income countries should be delivered at no cost to the recipient countries.

3.) Establish ongoing efforts to help global healthcare systems address COVID

The United States government should examine opportunities to implement broader initiatives that leverage the learnings of the President's Emergency Plan for AIDS Relief (PEPFAR). While the issues surrounding the COVID-19 pandemic are not exactly the same as the AIDS epidemic,

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elements such as White House leadership, close coordination with global allies, strong metrics and reporting mechanisms and commitments to invest in both developing country health systems and strategic partnerships for product access helped make the program a global health success.

- The Administration's Global Coronavirus Coordinator could lead this initiative by working closely with stakeholders to determine a set of activities that will positively impact both access to vaccines and therapeutics worldwide but also strengthen overall global preparedness.

- BIO and its members welcome the opportunity to work with the Administration on a PEPFAR-like set of initiatives that can provide mid and long-term solutions.

We acknowledge of course that this may not be the full universe of possible and practical solutions. BIO stands ready to work with the United States government and all key global parties to build on this framework and find such solutions.

Yours Sincerely,

Michelle McMurry-Heath, MD, PhD
President and Chief Executive Officer

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AMERICANS for TAX REFORM

Biden Admin Surrenders on American IP Rights

The Biden administration is backing a global effort to suspend all intellectual property (IP) rights for COVID-19 innovations, a move that would do little to help end the pandemic but would undermine U.S. medical innovation, jobs, and the Constitution.

Strong IP protections have facilitated the creation of several highly effective COVID-19 vaccines at a record pace.

Biden's decision to support an IP waiver for COVID-19 innovations will create a precedent that IP rights can easily be waived or undermined when government bureaucrats find it convenient. Surrendering on IP rights will also provide an implicit endorsement of the rampant theft of American IP by China. The U.S. should be doing more, not less to defend American IP.

Foreign countries like India and South Africa have been petitioning the World Trade Organization (WTO) to suspend IP rights associated with COVID-19 innovations.

According to the Washington Post, the administration's decision was made in a Tuesday meeting with President Biden. Commerce Secretary Gina Raimondo, who had concerns about the waiver, was not included in the meeting.

IP rights are explicitly protected in the constitution. The Founding Fathers recognized the importance of intellectual property rights in Article 1, Section 8 of the Constitution. "To promote the Progress of Science and useful Arts, by securing for limited times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

Strong IP rights are vital because they turn new ideas into tangible goods and services that improve the quality of life for Americans by creating high-paying jobs and increasing economic growth.

Without IP rights, medical innovators will have no incentive to create new treatments and cures as they will have no way to recoup the investments they made in developing new medicines. Patent exclusivity for medicines has been deliberately legislated to ensure that creativity, innovation, and medical growth are protected.

Because of these policies, the U.S. is a world leader when it comes to medical innovation. According to research by the Galen Institute, 290 new medical substances were launched worldwide between 2011 and 2018. The U.S. had access to 90 percent of these cures, a rate far greater than comparable foreign countries. By comparison, the United Kingdom had access to 60 percent of medicines, Japan had 50 percent, and Canada had just 44 percent.

Strong IP for medicines also supports millions of American jobs. Nationwide, the pharmaceutical industry directly or indirectly accounts for over four million jobs across the U.S and in every state, according to research by TEconomy Partners, LLC. This includes 800,000 direct jobs, 1.4 million indirect jobs, and 1.8 million induced jobs, which include retail and service jobs that are supported by spending from pharmaceutical workers and suppliers.

The average annual wage of a pharmaceutical worker in 2017 was $126,587, which is more than double the average private sector wage of $60,000.

Conservatives should oppose this effort to undermine IP rights.

Many lawmakers have rightly spoken out against this decision already. For instance, Senator Richard Burr (R-NC) and Ways and Means Republican Leader Kevin Brady (R-TX) have condemned Biden's decision to surrender on American IP protections. In addition, the Republican Study Committee announced in a tweet that Rep. Byron Donalds (R-Fla.) will be soon introducing a bill to prevent the Biden admin from undermining IP rights.

The Biden administration should reverse it's position. Rather than surrendering to foreign governments and global bureaucracies, the administration should stand strong and protect intellectual property rights.

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OPINION | REVIEW & OUTLOOK

Biden's Vaccine IP Debacle

His patent heist is a blow to the Covid fight and U.S. biotech.

By The Editorial Board
May 6, 2021 6:54 pm ET

President Joe Biden takes questions after delivering remarks on the Covid-19 response and the vaccination program from the State Dining Room of the White House on May 4.
PHOTO: ALEX EDELMAN - POOL VIA CNP/ZUMA PRESS

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6 minutes

We've already criticized President Biden's bewildering decision Wednesday to endorse a patent waiver for Covid vaccines and therapies. But upon more reflection this may be the single worst presidential economic decision since Nixon's wage-and-price controls.

In one fell swoop he has destroyed tens of billions of dollars in U.S. intellectual property, set a destructive precedent that will reduce pharmaceutical investment, and surrendered America's advantage in biotech, a key growth industry of the future. Handed an American triumph of innovation and a great soft-power opportunity, Mr. Biden throws it all away.

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India and South Africa have been pushing to suspend patents at the World Trade Organization for months. They claim that waiving IP protections for Covid vaccines and therapies is necessary to expand global access, but their motivation is patently self-interested.

OPINION: POTOMAC WATCH

Free Beer for the Vaccinated? States Try to Lure Arms

00:00 1x

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Both are large producers of generic drugs, though they have less expertise and capacity to make complex biologics like mRNA vaccines. They want to force Western pharmaceutical companies to hand over IP free of charge so they can produce and export vaccines and therapies for profit. Their strategy has been to shame Western leaders into surrendering with the help of Democrats in the U.S.

But suspending IP isn't necessary to expand supply and will impede safe vaccine production. The global vaccine supply is already increasing rapidly thanks to licensing agreements the vaccine makers have made with manufacturers around the world.

Pfizer and BioNTech this week said they aimed to deliver three billion doses this year, up from last summer's 1.2 billion estimate. Moderna increased its supply forecast for this year to between 800 million and a billion from 600 million. AstraZeneca says it has built a supply network with 25 manufacturing organizations in 15 countries to produce three billion doses this year.

AstraZeneca and Novavax have leaned heavily on manufacturers in India to produce billions of doses reserved for lower-income countries. But India has restricted vaccine exports to supply its own population. IP simply isn't restraining vaccine production.

Busting patents also won't speed up production, since it would take months for these countries to set up new facilities. Competition will increase for scarce ingredients, and less efficient manufacturers with little expertise would make it harder for licensed partners to produce vaccines.

There's also the problem of safety. Johnson & Johnson has experienced quality problems at an Emergent plant making its vaccines, and that's in Baltimore. Imagine the potential problems with unlicensed producers in, say, Malaysia or Brazil. If vaccines made there have complications, confidence in licensed vaccines could plummet too. And who would Pfizer and Moderna sue to get their reputations back?

The economic self-damage is also hard to fathom. The U.S. currently has a competitive advantage in biotech and biologics manufacturing, which could be a growing export industry. Waiving IP protections for Covid vaccines and medicines will give away America's crown pharmaceutical jewels and make the U.S. and world more reliant on India and China for pharmaceuticals.

Moderna has been working on mRNA vaccines for a decade. Covid represents its first success. Ditto for Novavax, which has been at it for three decades. Small biotech companies in the U.S. have been studying how to create vaccines using nasal sprays, pills and patches.

Thanks to Mr. Biden, all this could become the property of foreign governments. Licensing agreements allow developers to share their IP while maintaining quality control. Breaking patents and forcing tech transfers will enable China and low-income countries to manufacture U.S. biotech products on their own.

China's current crop of vaccines are far less effective than those in the West, but soon Beijing might be able to purvey Pfizer knock-offs. The U.S. has spent years deploring China's theft of American IP, and now the Biden Administration may voluntarily let China could reap profits from decades of American innovation.

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Instead of handing over American IP to the world, Mr. Biden could negotiate bilateral vaccine agreements and export excess U.S. supply. If Mr. Biden wants to increase global supply safely, the U.S. could spend more to help the companies produce more for export. Then the jobs would go to Americans. We thought this was the point of the production deal Mr. Biden negotiated between J&J and Merck.

Alas, this President seems to be paying more attention these days to Elizabeth Warren, Bernie Sanders, Alexandria Ocasio-Cortez and Nancy Pelosi. They think vaccines and new drugs can be conjured by government as a public good with no incentive for risk-taking or profit. This really is destructive socialism.

Mr. Biden ought to listen to Angela Merkel. Pfizer's partner BioNTech is a German firm, and the German Chancellor said Thursday that she opposes the WTO heist: "The protection of intellectual property is a source of innovation and it must remain so in the future."

At least IP is safe in Germany. Mr. Biden has sent a signal around the world that nobody's intellectual property is safe in America.

Appeared in the May 7, 2021, print edition.

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OPINION | POTOMAC WATCH

President Joe Sanders

The vaccine patent decision is the latest example of Biden's far-left governance.

By

Kimberley A. Strassel

May 6, 2021 6:33 pm ET

A nurse prepares a shot of the Johnson & Johnson vaccine for Covid-19 in New York, April 8.

PHOTO: MARY ALTAFFER/ASSOCIATED PRESS

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The White House this week proposed to strip drug companies of their vaccine patents, an act hailed by adulators as "moral leadership." It's better seen as the encapsulation of the Biden presidency—a case study in fictional narratives, executive overreach, recklessness, and kowtowing to the left.

The biopharmaceutical industry in under a year accomplished a modern miracle—designing a breakthrough vaccine to counter Covid-19; engineering a ground-up production process; and climbing a logistical Everest. It was a triumph of innovation, investment and capitalism, a moment that deserves to be celebrated.

OPINION: POTOMAC WATCH

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Instead, the Biden administration supports a proposal in the World Trade Organization that would "waive" the intellectual-property rights of the companies that accomplished this feat, giving away their technology to every drugmaker in the world. Put another way, Mr. Biden is freely handing American invention to China—the country that routinely steals it, and whose Wuhan lab might have been the source of the virus.

The move is in keeping with the administration's refusal to acknowledge the history of the vaccine achievement. Team Biden continues its willful disregard of Operation Warp Speed, in part because it is too petty to give credit to any person, company or initiative connected to the Trump administration.

It has instead pushed the claim that the Biden administration alone deserves credit for the vaccine rollout. This rewriting of reality is becoming routine. The administration declares there is no "crisis" at the border, as illegal crossings surge. It says Georgia's election-law update is "Jim Crow," although the state provides more voting opportunities than others. It redefines entitlement spending as "infrastructure." The press only encourages these fictions, making it easier for the administration to ignore biotech's lead role in beating the pandemic and to hand over its work to the world.

The move is also in keeping with the administration's attitude that Congress exists solely to rubber-stamp its spending proposals. Congress has spent decades wrangling over the contours of patent protections, producing bipartisan legislation from the Bayh-Dole Act of 1980 and the Hatch-Waxman Act of 1984 to the Leahy-Smith Act of 2011. Mr. Biden proposes to disregard all these laws with the wave of an executive memo to the WTO—much as he has already been governing by dubious executive orders on immigration, mask mandates, pipeline cancellations, and healthcare. Mr. Biden will use Congress when

reconciliation makes it convenient. But what Congress won't give him, he will decree unilaterally.

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The patent decision is also in line with the Biden administration's willingness to take wild steps with little thought or care about the damaging consequences. No doubt it is glorying in the praise from the World Health Organization. But the precedent of willy-nilly canceling patents will prove cataclysmic for drug innovation and health. Moderna spent 10 years developing its mRNA technology, and only this week turned its first profit. Next pandemic, Moderna and other companies won't bother. The same is true of cancer drugs, Parkinson's therapies, even new antibiotics. Don't believe it? "Let's do insulin next," tweeted an exultant Rep. Alexandria Ocasio-Cortez in response to the patent news, along with a graph showing the plunge in vaccine makers' stock prices.

Add this to an extraordinary list of unknowns and unintended consequences imposed in only three short months. What will the Biden administration's expansion of ObamaCare (part of its Covid "relief" law) do to healthcare prices? Do they know? What is the fallout of shoveling some $200 billion at schools that aren't educating kids? The February spending bill extended enhanced federal unemployment benefits to September, which means restaurants can't get employees to come back to work. So this week the Biden administration touted its new Restaurant Revitalization Fund—a government fix to the government's blunder.

Mostly, the patent decision showcases who is in charge. It isn't Mr. Biden. Progressives have been calling for patent waivers since last year, and Bernie Sanders, Elizabeth Warren and AOC amped up the pressure on Mr. Biden in the past month. These voices won out—

again—over those in the administration who noted that waiving patent protections isn't the answer. Even the administration's Covid guru, Anthony Fauci, this week told the Financial Times that the patent release will likely get bogged down in lawsuits, and "there are other ways to ramp up vaccine production around the world."

In a debate with Mr. Trump last year, Mr. Biden testily asserted that *he* is "the Democratic Party right now"; what he says goes. But name one progressive demand he hasn't rolled over for. This is a Sanders presidency by another name.

The patent decision is only the latest example, and surely not the last. It's going to be a long, and destructive, few years.

Write to kim@wsj.com.

Appeared in the May 7, 2021, print edition.

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PRESS RELEASE

Patent Waiver Strikes Damaging Blow to the Future of Innovation

Dr. Stephen J. Susalka, CEO of AUTM, a global Association whose Members guide research from the lab to the marketplace, issued a statement denouncing the Biden administration's decision to back the suspension of patents for COVID-19 vaccines.

"As an organization that drives research commercialization from universities and other public sector research institutions, we are deeply troubled that the White House would strike this damaging blow to intellectual property (IP) protections and innovation. Eliminating IP rights is a mirage that will have a limited near-term effect and a devastating long-term result.

The biggest factors impeding vaccine access in developing economies are manufacturing know-how, resources and infrastructure - not IP rights. Indeed, the ability of the biotech industry to respond so quickly to the need for COVID-19 vaccines was *because* of IP protections. [AUTM itself developed COVID-19 Licensing Guidelines, adopted by almost 100 well-known institutions, to support time-limited, non-exclusive royalty-free licenses for COVID technologies.]

Unfortunately this decision to weaken patent rights will result in less future investment and fewer new, competing vaccines for COVID-19 — or the next pandemic. Long-term, it will have a chilling effect on the translation of transformative ideas (like mRNA vaccines) and reduce investment in exactly the kind of early-stage innovation that this Administration touts as the future of the economy.

Ironically, had this proposed policy been in place prior to the spread of this coronavirus, the obvious question to ask is whether any company would have made the substantial investment

in foundational technology to support the development of these vital vaccine products. Undermining the processes that brought vaccines to the public in record time is a mistake and will have repercussions well into the future. Moving forward with this waiver, in lieu of other more impactful approaches, such as increased manufacturing and exporting vaccine supply, puts future investment, solutions, and opportunities at risk. Strong IP rights incentivize the costly process of bringing products to market — this TRIPS patent waiver threatens to ruin that critical balance."

About AUTM

AUTM is the non-profit leader in efforts to educate, promote and inspire professionals to support the development of academic research that changes the world and drives innovation forward. Our community is composed of more than 3,000 members who work in more than 800 universities, research centers, hospitals, businesses and government organizations around the globe.

Dr. Susalka is available for interviews.

Media Contacts

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Novavax Statement in Opposition to the WTO TRIPS Waiver

May 7, 2021

Novavax is committed to accelerating equitable access to safe and effective COVID-19 vaccines, particularly in countries where vaccination rates are low. On May 6, 2021 we again demonstrated this commitment through the finalization of an advance purchase agreement with Gavi, which in conjunction with our partner Serum Institute of India, will supply a cumulative 1.1 billion doses of our recombinant protein-based COVID-19 vaccine candidate to the COVAX Facility. This means actual shots in arms for millions of people around the globe in low, middle, and high-income countries based on principles of equitable access. The WTO TRIPS waiver and similar proposals to weaken intellectual property protection would not achieve equitable vaccine access, and instead has the very real potential to undermine Novavax' ability to fulfill our commitment.

The ability to deliver vaccines relies upon access to limited raw materials and consumables; strong partnerships with capable manufacturers; and free movement of supplies and vaccines between countries. A TRIPS waiver could further constrain resources by diverting them to entities incapable of manufacturing safe and effective vaccines in the near term. A TRIPS waiver could also undermine existing partnerships and would not promote timely capacity-building. Even under the best circumstances, it can take years to stand up the manufacturing capabilities required to safely produce vaccines. A TRIPS waiver could increase national barriers to the free flow of materials and vaccine doses, threatening the stability and integrity of the global supply chain. Furthermore, a TRIPS waiver could contribute to the proliferation of counterfeits throughout the world, undermining the safety of the entire vaccine supply.

From the outset, Novavax has worked to implement broad manufacturing capacity and thereby access to our vaccine in as many parts of the world as possible. Novavax took the initiative to partner with dozens of organizations to take advantage of every opportunity to grow capacity. During this pandemic, we have forged over 25 partnerships in more than 10 countries to ensure equitable and global access to our COVID-19 vaccine candidate. We have spent months transferring knowhow to our partners to ensure they are able to manufacture doses that meet regulators' standards for safety and effectiveness around the world.

With COVID-19 infections continuing to surge around the world, vaccine developers are united in a race against the virus to minimize transmission rates and to prevent the emergence and circulation of new variants. No one is safe until everyone is safe. A TRIPS waiver is not the right answer. It will not achieve its intended purpose. Instead, governments should support existing partnerships and encourage new voluntary collaborations; facilitate and expedite the export of materials necessary to manufacture and finish vaccines; and work together to ensure a safe and secure global supply of vaccines.

Congress of the United States
Washington, DC 20515

April 27, 2021

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, Southwest
Washington, D.C. 20201

Dear Secretary Becerra:

As Members of the Texas Congressional Delegation, we are disappointed with and concerned by the Centers for Medicare and Medicaid Services' (CMS) action taken on Friday, April 16, 2021 to rescind the 10-year extension of Texas' Medicaid 1115 Waiver. The previous Administration's extension of this waiver on January 15, 2021 through September 30, 2030 provided much-needed certainty to the State to plan financially for future years of medical care for our State's most vulnerable citizens. This unprecedented action by CMS jeopardizes billions of dollars in funding for Texas' Medicaid program. Rescinding this waiver extension threatens the security of the State's Medicaid program, disrespects the continuity of this agreement, and erodes the partnership between the State and CMS. Additionally, this action deters future State innovation in the Medicaid program and will negatively impact the level of trust between States and the agency.

More than four million Texans, including half of all children in the State, depend on the stability of the State's Medicaid program for quality health care for themselves and their families. Revoking the extension of Texas' 1115 Waiver pulls the rug out from beneath these patients and puts their health care at risk. Hospitals and providers in the State have been pushed to the brink and stretched thinner than ever before during the COVID-19 pandemic. The 10-year extension of the 1115 Waiver granted in January 2021 established much needed certainty for years to come so that the State would not have to navigate complex negotiations to change its Medicaid financing mechanisms, especially after the strain the system faced during the COVID-19 pandemic.

A long extension provides hospitals with financial security to plan how they will care for patients in future fiscal years. The action taken by CMS to rescind this previously approved waiver extension undermines the safety net and the ability of hospitals to provide quality care to Medicaid and uninsured patients. The Texas Hospital Association published a white paper entitled "The Medicaid 1115 Waiver is a Building Block to Health Coverage" on February 12, 2021, explaining the critical role the extension of the 1115 Waiver plays in funding health coverage for Texans who are insured by Medicaid or uninsured. In the midst of the COVID-19 pandemic, it is particularly critical that hospitals have the ability to plan ahead for their financial

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stability and uncompensated care costs. Rescinding this waiver extension directly threatens care for this vulnerable population.

This waiver extension also established a transition away from the Delivery System Reform Incentive Payment System (DSRIP) towards a new Public Health Provider charity care pool and directed payment programs during the COVID-19 pandemic. The State is already several months into working with CMS to establish new directed payment programs. Rescinding the waiver extension creates uncertainty for the programs that need to be operational by October 1, 2021. These new directed payment programs include a new uncompensated care pool for local health departments and community mental health centers, a Comprehensive Hospital Increased Reimbursement Program, Texas Incentives for Physician and Professional Services, Rural Access to Primary and Preventive Services, and others. These new programs will improve access and quality of care for patients. Texans should have the opportunity to receive these enhanced services into the future, not just for one year.

The time and effort required to renegotiate a new waiver extension will detract from the work that Texas and your agency could be conducting to improve health care for Texans and for Americans. We respectfully request that CMS reconsider the egregious and unprecedented action it has taken to rescind this 1115 Waiver extension. We urge you to work closely with Texas going forward.

Thank you for your time and attention to this important matter that will gravely impact our State's ability to provide Medicaid services to Texans.

Sincerely,

Michael C. Burgess, M.D.
Member of Congress

John Cornyn
United States Senator

Ted Cruz
United States Senator

Kevin Brady
Member of Congress

Dan Crenshaw
Member of Congress

Jodey C. Arrington
Member of Congress

Brian Babin, D.D.S.
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Louie Gohmert
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Beth Van Duyne
Member of Congress

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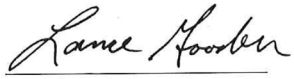
Van Taylor
Member of Congress



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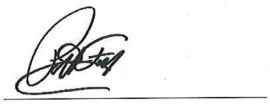

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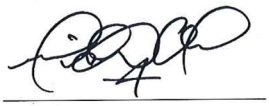
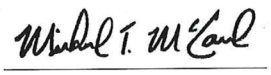


Michael Cloud
Member of Congress



Michael T. McCaul
Member of Congress

Ronny L. Jackson, M.D.
Member of Congress

Randy K. Weber
Member of Congress

Tony Gonzales
Member of Congress

John R. Carter
Member of Congress

Congress of the United States
House of Representatives
Washington, DC 20515

February 26, 2021

Acting Secretary Cochran
Department of Health and Human Services
200 Independence Ave SW
Washington DC 20201

Dear Acting Secretary Cochran,

We write today as leading congressional proponents of the 340B drug discount program to ask you to take immediate action to ensure that manufacturers are prohibited from imposing unilateral changes to the program in direct conflict with congressional intent and decades of written guidance.

We were pleased to see 28 attorneys general urge former HHS Secretary Azar to protect the 340B program.[1] We believe that letter and the Department's Office of General Counsel's advisory opinion, released on December 30 and described below, represent some of the most compelling legal arguments for the actions we ask you to take.

As you know, Congress enacted the 340B Drug Pricing Program in 1992 following the creation of the Medicaid Drug Rebate Program. In order for their drugs to be covered by Medicaid, manufacturers are required to offer discounts to certain public and nonprofit health care organizations known as covered entities, including Federally Qualified Health Centers, Ryan White HIV/AIDS Clinics, Medicare/Medicaid Disproportionate Share hospitals, rural hospitals, and children's hospitals. According to the legislative history, Congress's intent in creating the discount program was to "stretch scarce federal resources to reach more eligible patients and provide more comprehensive services."

The 340B statute requires drug manufacturers to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price."[2] There are no provisions in the statute that allow manufacturers to set conditions or otherwise impede a provider's ability to access 340B discounts. The Health Resources and Services Administration (HRSA), which oversees the program, has indicated on multiple occasions, dating back to the early years of the program, that the 340B statute requires manufacturers to provide 340B discounts to covered entities when covered entities purchase drugs to be dispensed through contract pharmacies on a covered entity's behalf.[3]

Beginning in the summer of 2020, several drug manufacturers began to announce a range of actions to avoid honoring 340B discounts for certain drugs, many with the highest prices, delivered to covered

[1] https://portal.ct.gov/-/media/AG/Press_Releases/2019/340B-Multistate-Letter-12142020_FINAL1.pdf (Drug Manufacturers' Actions Violating 340B Drug Pricing Program Requirements)
[2] 42 U.S.C. § 256b(a)(1).
[3] Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549 (Aug. 23, 1996); Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 43 Fed. Reg. 10272, 10278 (March 5, 2010).

entities' contract pharmacies. Some manufacturers have announced they will no longer ship discounted drugs to contract pharmacies; others will ship to only one contract pharmacy per covered entity.

HHS has reviewed manufacturers' refusals to provide 340B discounts to covered entities' contract pharmacies and found them to be unlawful. In a December 30th 2020 advisory opinion, then-general counsel Robert Charrow wrote, ""[T]he core requirement of the 340B statute...is that manufacturers must "offer" covered outpatient drugs at or below the ceiling price for "purchase by" covered entities. This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs."[4]

Unfortunately, publishing the advisory opinion has not deterred manufacturers from continuing with unlawful price hikes. Many covered entities are struggling with severe financial losses as a result of the COVID-19 pandemic. They cannot afford to be unfairly targeted by large pharmaceutical corporations or be forced to pay higher up-front costs for the drugs their patients need.

Furthermore, an information technology company has allied with manufacturers to change the 340B program from one of upfront discounts to post-sale rebates, a change that would greatly increase costs for covered entities and give manufacturers tremendous leverage over covered entities. Such action is inconsistent with HRSA's long-standing guidance that the 340B program is an up-front discount program.[5]

The December 14th letter from the attorneys general called on HHS to "address drug manufacturers' unlawful refusal to provide critical drug discounts to covered entities." Consistent with that letter, we urge you to:

1. Begin assessing civil monetary penalties on manufacturers that deny 340B pricing to covered entities in violation of their obligations under the 340B statute;
2. Require manufacturers to refund covered entities the discounts they have unlawfully withheld since 2020;
3. Halt, through guidance or other means, any attempt to unilaterally change 340B upfront discounts to post sale rebates; and
4. Immediately seat the Administrative Dispute Resolution Panel to begin processing disputes within the program.

As the attorneys general stated in their December 14th letter, "Each day that drug manufacturers violate their statutory obligations, vulnerable patients and their health care centers are deprived of the essential healthcare resources Congress intended to provide." Thank you very much for your prompt consideration of these important matters.

CC: California Attorney General Xavier Becerra

Sincerely,

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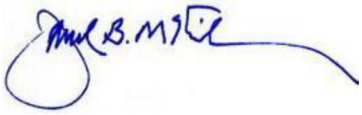
[4] HHS, Advisory Opinion 20-06 On Contract Pharmacies Under The 340B Program (Dec. 30, 2020).
[5] Limitation on Prices of Drugs Purchased by Covered Entities, 58 Fed. Reg. 27289, 27291 (May 7, 1993); Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25110, 25113 (May 13, 1994).

Abigail D. Spanberger
Member of Congress



David B. McKinley
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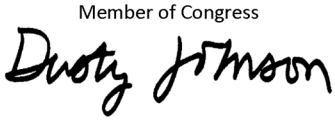

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Vicky Hartzler
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Member of Congress

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Jaime Herrera Beutler
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Clay Higgins
Member of Congress

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Brian Higgins
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Andy Kim
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Susie Lee
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Sheila Jackson Lee
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Ron Kind
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Mike Levin
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Chris Jacobs
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Raja Krishnamoorthi
Member of Congress

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Andy Levin
Member of Congress

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Sara Jacobs
Member of Congress

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Ann McLane Kuster
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Ted W. Lieu
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Ro Khanna
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Al Lawson
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Nicole Malliotakis
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Derek Kilmer
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Seth Moulton
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Lucy McBath
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A. Donald McEachin
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Eleanor Holmes Norton
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Ayanna Pressley
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Ilhan Omar
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Chris Pappas
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Guy Reschenthaler
Member of Congress

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Hal Rogers
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John Rose
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Lucille Royal-Allard
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Raul Ruiz, M.D.
Member of Congress

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C.A. Dutch Ruppersberger
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Bobby L. Rush
Member of Congress

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John H. Rutherford
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Tim Ryan
Member of Congress

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Gregorio Kilili Camacho Sablan
Member of Congress

_____/s/_____
Michael F.Q. San Nicolas
Member of Congress

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Linda T. Sánchez
Member of Congress

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John P. Sarbanes
Member of Congress

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Mary Gay Scanlon
Member of Congress

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Jan Schakowsky
Member of Congress

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Adam B. Schiff
Member of Congress

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Bradley S. Schneider
Member of Congress

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Kim Schrier, M.D
Member of Congress

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Austin Scott
Member of Congress

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Pete Sessions
Member of Congress

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Terri A. Sewell
Member of Congress

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Mike Simpson
Member of Congress

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Albio Sires
Member of Congress

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Adam Smith
Member of Congress

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Darren Soto
Member of Congress

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Jackie Speier
Member of Congress

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Greg Stanton
Member of Congress

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Pete Stauber
Member of Congress

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Elise M. Stefanik
Member of Congress

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Steven Horsford
Member of Congress

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Haley Stevens
Member of Congress

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Chris Stewart
Member of Congress

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Steve Stivers
Member of Congress

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Mark Takano
Member of Congress

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Bennie Thompson
Member of Congress

_____/s/_____
Mike Thompson
Member of Congress

_____/s/_____
Glenn "GT" Thompson
Member of Congress

_____/s/_____
Tom Tiffany
Member of Congress

_____/s/_____
Dina Titus
Member of Congress

_____/s/_____
Paul Tonko
Member of Congress

_____/s/_____
Norma J. Torres
Member of Congress

_____/s/_____
Lori Trahan
Member of Congress

_____/s/_____
David Trone
Member of Congress

_____/s/_____
Lauren Underwood
Member of Congress

_____/s/_____
Fred Upton
Member of Congress

_____/s/_____
Jefferson Van Drew
Member of Congress

_____/s/_____
Juan Vargas
Member of Congress

_____/s/_____
Filemon Vela
Member of Congress

_____/s/_____
Ann Wagner
Member of Congress

_____/s/_____
Debbie Wasserman Schultz
Member of Congress

_____/s/_____
Bonnie Watson Coleman
Member of Congress

_____/s/_____
Peter Welch
Member of Congress

_____/s/_____
Jennifer Wexton
Member of Congress

_____/s/_____
Susan Wild
Member of Congress

_____/s/_____
Nikema Williams
Member of Congress

_____/s/_____
Frederica S. Wilson
Member of Congress

_____/s/_____
Robert J. Wittman
Member of Congress

_____/s/_____
John Yarmuth
Member of Congress

_____/s/_____
Don Young
Member of Congress

Biden's monumental World Trade Organization Covid mistake

getliberty.org/2021/05/bidens-monumental-world-trade-organization-covid-mistake/

press May 10, 2021

"President Biden's decision to allow a waiver of intellectual property provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement for newly developed medicines and vaccines at the World Trade Organization is a monumental mistake that threatens continuing innovation and the current and future distribution of the vaccine in the fight against the Covid-19 virus.

"The cutting-edge innovation which has led to the development of four separate vaccines including two that use mRNA technology will effectively be distributed around the world under the guise of providing additional help to populations that have not received vaccinations. While this may seem noble on its face, the net result of the Biden action will likely be the end of new innovations on treatment and better vaccines and boosters. The Trump administration rejected the WTO waiver as it effectively allows a quantum technological leap in bio-weapon development in countries that don't like the United States very much.

"Furthermore, it is doubtful that the waiver will produce many additional vaccines because the world is years behind in mRNA technology, meaning there are not many places with the skill to create them in a mass manufacturing setting. The short-term result will be in straining supply chains and result in counterfeit vaccines being created at a time when health professionals need to trust what they're administering. We're still going to have to produce most of this and all that's changed is we'll be required distribute limited supplies everywhere, allowing the world to raid our supply. Next fall, if this results in a slowdown in the U.S. of vaccine distribution for any further boosters that might be needed, it will fall on Biden's head. However, those scientists and government's intent on bio-weaponry development, including China which is in a race to develop a bio arsenal, may get answers on how a weapon might be defeated, making the world a less safe place.

"We urge President Biden to reconsider this decision. It won't significantly increase the number of vaccines available, encourage development of even more advanced treatments and vaccines, while increasing our national security risks."

For media availability contact Catherine Mortensen at 703-478-4643
or cmortensen@getliberty.org.

###

Impact of the Texas 1115 Waiver Extension Rescission on Children's Hospitals

The Children's Hospital Association of Texas (CHAT) and the seven children's hospitals it represents have significant concerns about the rescission of the ten-year extension of Texas' Medicaid 1115 Waiver. CMS's rescission introduces significant uncertainty for providers who treat children covered by Medicaid in Texas, including children with the most medically complex conditions that often require care provided only by children's hospitals.

Children Depend on Medicaid and Children's Hospitals in Texas.

- **Medicaid is a primary payor for care in children's hospitals**, as between 50 and 80 percent of inpatient days in children's hospitals are paid for by Medicaid.
- **Often a children's hospital is the only place that a child can get the care that he or she needs**.
  - Almost 70% of the children seen at a children's hospital in Texas are severely ill, compared to just 40% seen at non-children's hospitals.
  - Children's hospitals care for kids suffering from the most extreme illnesses—cancer, organ failure, cystic fibrosis, and sickle cell disease.
  - Due to the size of the Texas, children's hospitals serve as a safety net for critically ill children who may not have alternatives for specialized care or treatment in their region of the state.

Uncertainty of the Waiver means Uncertainty for Children's Hospitals and the Kids They Treat.

- **With the future of the waiver unknown, the financial future of children's hospitals remains uncertain.** This is because the savings generated through the waiver (budget neutrality) determine how much Medicaid funding is available to Texas providers for supplemental payment programs. The waiver extension allowed Texas to continue managed care as its primary healthcare delivery system and provided needed time to transition the Delivery System Reform Incentive Payment (DSRIP) innovations begun under the waiver.
- **Over time, children's hospitals have been less able to benefit than other hospital classes from supplemental payment programs** like the Medicaid Disproportionate Share Hospital (DSH) program and the Uncompensated Care (UC) program, which serve to supplement the difference between the cost of providing Medicaid services and what Medicaid reimburses for these services.
- **Hospital rate increase payment programs are extremely important to ensure stability in Medicaid funding and continued access to care in children's hospitals.**

Children's Hospitals Need CMS to Work with the State to Ensure the Pediatric Safety-Net is Not Hurt.

- **Children's hospitals request that CMS approve the Comprehensive Hospital Increase Reimbursement Program (CHIRP) including the program structure and size submitted by Texas.** This program allows children's hospitals to continue to meet the needs of all children in the state and ensures that all children have access to life-saving care. This program builds on DSRIP best practices so that, to earn funding, children's hospitals must meet targeted quality metrics for pediatric populations and demonstrate how they are improving care and healthcare outcomes. Over a billion dollars of funding to support children's hospitals throughout the state is at risk.
- **Children's hospitals request that CMS work closely with the state to resolve the waiver negotiations quickly and in a manner that does not adversely impact the pediatric safety-net.** The outcome of the waiver could have a direct impact on the Medicaid funding available to children's hospitals that treat severely ill children in Texas. Children's hospitals could lose $84 million in uncompensated care funding per year if the waiver is not extended. Children's access to lifesaving care, especially those with medically complex conditions, available in children's hospitals is critical for the future of the state.

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OPINION | COMMENTARY

Patent Busting Won't Help Vaccinate the World Faster

The solution is to ease restrictions on exporting shots and build more production capacity.

By Luciana Borio and Scott Gottlieb
May 9, 2021 4:12 pm ET

A worker prepares Covid-19 vaccines for shipment in Olive Branch, Miss., Dec. 20, 2020.
PHOTO: PAUL SANCYA/POOL/SHUTTERSTOCK

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5 minutes

While the U.S. Covid pandemic has been contained, the situation in many countries, particularly India, is dire. It's essential to get as much of the world vaccinated as quickly as possible to save lives and prevent new variants from emerging. The Biden administration's support for breaking vaccine patents is a bad precedent that would do no immediate good and substantial long-term harm.

There isn't enough vaccine supply to meet world-wide demand. Many countries have access only to inferior vaccines produced in Russia or China. Understandably, they want

the same safe and effective vaccines that are available to Americans. By the end of 2022, U.S. manufacturers will produce more than 12 billion doses of high-quality vaccines, enough to satisfy global needs. And other vaccine candidates are in the pipeline and may be authorized over the next year. But over the next six months, global supply will remain tight.

OPINION: POTOMAC WATCH

Biden Wants to Trample Covid-19 Vaccine Patents

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The Biden administration caved to pressure at the World Trade Organization to support waiving intellectual-property protections for Covid vaccines. Some activists have declared victory, even though patent breaking wouldn't solve the immediate problem and could make a global agreement much more difficult. France, Germany and the U.K. all oppose the idea, and the WTO should reject it. Here are four productive steps the developed world could take instead:

First, the U.S. government should stop hoarding doses and make them available for export. Some of the biggest vaccine makers have shown that their manufacturing is stable and growing. The supply chain is reliable, and the U.S. doesn't need to stockpile hundreds of millions of doses. More can be made available on a rolling basis to countries like India and Brazil.

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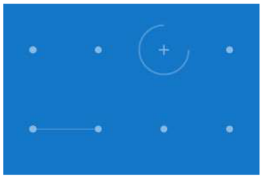
Second, countries that produce quality vaccines such as Belgium, France, Japan, Australia and the U.K., to name only a few, should invest in a major expansion of manufacturing facilities and the attendant supply chain, in return for a guarantee that a high percentage of the vaccines that flow from these efforts go to low- and middle-income nations. This would secure stable production and guarantee a steady supply of high-quality vaccines for vulnerable nations.



An ultra-short municipal bond ETF seeking to solve income challenges

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Third, the U.S. should work with the World Health Organization to deal with legitimate liability concerns from U.S. manufacturers that donate vaccines to low-income nations. Companies are worried about being sued by all manner of individuals all over the world. Patients need recourse if they're harmed, and vaccine companies need some backstop on unbounded liabilities. This could take the form of a compensation system for injuries, overseen by the World Bank. Similar measures are in place for manufacturers that make doses available to Americans under an emergency-use authorization.

Finally, American drug makers can work with existing vaccine manufacturers in middle-income nations such as Brazil and South Africa. Some of these countries may be able to expand their capacity to take on international "fill and finish" capacity, receiving vaccines in bulk and placing them in smaller vials for distribution, the insufficiency of which could otherwise become a bottleneck. These kinds of tech transfers could take time—at least six months and probably a year or longer—and would need to be started in short order.

All these steps depend on a global agreement to protect intellectual property. The proposal to suspend portions of the WTO's agreement on intellectual property has long been sought by China as a way to pirate Western intellectual property legally. Drug makers can work exclusively with leaders in the European Union to put together a package that would address immediate and long-term needs of lower-income nations while continuing to protect intellectual property, which is vital to the development of future vaccines and therapies.

Many nations are still suffering deeply from Covid-19. There's no time to waste on symbolic measures that set a poor precedent and don't solve the crisis.

Dr. Borio is a senior fellow for global health at the Council on Foreign Relations and was Director for Medical and Biodefense Preparedness at the National Security Council, 2017-19. Dr. Gottlieb is a resident fellow at the American Enterprise Institute and a board member of Pfizer. He was commissioner of the Food and Drug Administration, 2017-19.

Appeared in the May 10, 2021, print edition.

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https://www.washingtonexaminer.com/news/north-carolina-city-next-house-migrant-children

Washington Examiner

NEWS

North Carolina city could be next to house unaccompanied migrant children

by Anna Giaritelli, Homeland Security Reporter | May 07, 2021 02:08 PM

GREENSBORO, North Carolina — The Biden administration is in talks with city officials in Greensboro to open an overflow shelter that would hold hundreds of unaccompanied migrant children who have come across the southern border, according to the city.

The U.S. Department of Health and Human Services is eyeing the American Hebrew Academy, a shuttered international boarding school, as its next site to hold up to 800 children, city officials revealed.

"On Tuesday, May 4, both City and County officials met with representatives from the US Department of Health and Human Services to conduct a site assessment of the American Hebrew Academy facility at 4334 Hobbs Rd. The facility is one of several sites across the country identified as unused property for potential use as a temporary influx housing for unaccompanied children," the city of Greensboro said in a statement on Thursday.

The city said it did not initiate this proposal and that the Biden administration reached out to Greensboro. The boarding school closed in 2019 due to financial troubles.

HHS has visited the Greensboro site twice in recent weeks and is not expected to announce its decision until the summer. HHS would contract medical, security, food, and other services for the site, but Greensboro Mayor Nancy Vaughan claimed it could lead to "as many as 800 jobs" for local residents. The federal government would provide on-site security and medical needs, independent of city and county resources.

The move would make it among more than a dozen emergency facilities nationwide to hold the nearly 22,000 children in HHS custody due to the government's shortage of existing sites. Record-high numbers of children have been showing up at the border without parents, oftentimes pushed across after self-separating from a family to take advantage of President Joe Biden's border policy enforcement.

In March 2020, the Trump administration opted not to arrest anyone who illegally crossed the border and instead turned them back so that Border Patrol stations would not become crowded with people amid the coronavirus pandemic. In February, the Biden administration chose to stop turning away children, which resulted in more than 18,000 single children showing up at the U.S.-Mexico border in March, the most recorded in a single month.

Since January, the government has spent approximately $3 billion on costs associated with housing children who have crossed the southern border.

https://www.abc15.com/news/national/valley-family-pleads-with-fda-for-access-to-experimental-drug-for-fatal-childrens-disease

abc15 ARIZONA

NEWS > NATIONAL NEWS

Valley family pleads with FDA for access to experimental drug for fatal children's disease

By: Sonu Wasu
Posted at 9:45 PM, May 10, 2021
and last updated 11:50 PM, May 19, 2021

Denise and Rickey Miller are pleading for help, knowing time could be running out for their 21-month-old son Woodrow, who is diagnosed with a rare disease called Niemann-Pick Disease Type-C.

Denise Miller describes it as a rare disease that is fatal 100 percent of the time.

"There are roughly 100 kids in the United States with this disease, 500 in the world," said Denise.

Some believe the medication to help children like Woodrow is out there, but the pharmaceutical company behind the drug Adrabetadex says there is no proof the drug works, so they will no longer be making it available to patients after October 2021.

The Millers say they've heard amazing stories from families who have used this experimental drug and they've been on a mission to allow their son access to the drug hoping it could help prolong his life.

Woodrow was born seven weeks premature. He has bright blue eyes, a big smile, but a liver that is barely functioning.

Niemann-Pick Disease is likened to a form of childhood Alzheimer's by some. The devastating genetic disease eventually takes away a child's ability to walk, talk, swallow, eat, and breathe, as it weakens their muscles, brain, hearing, sight, and motor skills.

Denise quit her full-time job as a nurse to work full time caring for her son.

"Our daily life right now is consumed with doctor's appointments, therapies, speech therapy, occupational therapy," said Denise.

She added that Niemann-Pick Disease is 100% fatal 100% of the time, but treatments like Adrabetadex have shown to slow down the progression of the disease, allowing children to live longer lives.

Some parents ABC15 spoke with did not think their children would survive past the age of three, but they are now well into their teens and doing well. These parents credited Adrabetadex for their children's good health.

That is why the Millers are so desperate to at least try the drug on their child to see if it will make a difference. Rickey said over the last couple of months they have already seen Woodrow's ability to walk and swallow getting weaker. They're worried that without any medication, statistically, he could live for only about one more year.

"Within that year he will lose every skill, every ability he has and go into a vegetative state until the day he dies," said Denise.

There was no cure for Niemann-Pick Disease Type C. Many families feel Adrabetadex provides them with hope of being able to spend more quality time with their children. Some parents have testified that after starting the drug, their children started doing things they never thought possible, such as running and climbing trees, or being able to read, and put together full sentences.

This hope for many families is soon coming to an end, as the company that has been developing the drug has decided to stop production of Adrabetadex, citing clinical trials that did not show promising results. The company is allowing about 40 children who are already using the drug until October 2021 before cutting off access.

Woodrow is not one of those children. Miller has been writing letters to pharmaceutical company officials, FDA officials, and lawmakers begging to allow Woodrow access to this drug, as his body continues to get weaker.

"It's the most hopeless feeling, knowing that there is a medication literally sitting on a shelf across the country that 40 other children are getting access to, and that Woodrow is being denied access to," said Denise.

In a letter to families, officials with Mallinkrodt expressed regret saying the clinical trials they had been conducting with the drug did not go far enough.

ABC15 reached out Mallinkrodt officials to get more information on these clinical trials. A company official sent us this statement:

"Mallinckrodt deeply acknowledges the disappointment the community, families and patients are experiencing as a result of our decision to discontinue the development of Adrabetadex as a potential treatment for Niemann-Pick Type C (NPC) disease. Over the years, we have come to know many of the families and children impacted by NPC, and like them, we sincerely wish the outcome had been different.

Since acquiring the drug in 2018, Mallinckrodt invested substantially in investigating Adrabetadex as a possible treatment for this ultra-rare and devastating disease. Throughout this process, we have worked closely with the U.S. Food and Drug Administration (FDA) and other regulatory authorities, the National Institutes of Health (NIH), study investigators and NPC experts, seeking their input and guidance.

We are aware that some families and their physicians report seeing benefit in children being treated with Adrabetadex. These reports and case studies were the reason we were hopeful the scientific study would also demonstrate evidence of benefit for patients with NPC. However, after exhaustive analysis of clinical data, there is no clear evidence that Adrabetadex changes or improves disease progression across the group of patients that were studied. An independent data and safety monitoring review board evaluated these data and outcomes and agreed with our assessment. This decision was difficult for Mallinckrodt as we recognize the critical need for new treatment options for NPC and know how hopeful the NPC community was that Adrabetadex would become available for widespread use.

As we announced publicly in January of this year, we will continue to provide Adrabetadex through October 2021 to existing eligible patients already receiving treatment in current studies and expanded access programs. This will allow time for physicians and patients/families to develop a plan for when Adrabetadex is no longer available.

We are deeply grateful to the patients, caregivers, clinicians and patient advocacy groups for their participation and support of the Adrabetadex clinical development program. We remain hopeful that new treatment options for NPC are on the horizon."

ABC15 then asked Mallinkrodt officials why all children diagnosed with Niemann-Pick disease could not have access to the drug until October 2021 if they chose to do so.

In a follow-up statement, a spokesman said:

"When Mallinckrodt announced the determination of the negative risk balance of Adrabetadex in January 2021, we committed to continuing access to the drug for eligible patients for treatment for up to nine months, as these patients transitioned to other potential treatment options and/or care. We consulted with the FDA on the decision to discontinue development while still allowing access to the drug for this additional nine-month period. During this consultation, Mallinckrodt and the FDA agreed to very stringent criteria in recognition of the negative benefit/risk profile for the drug. As part of this criteria, it was agreed that no new patients will be able to start Adrabetadex, and we will not be able to initiate any new company-sponsored clinical studies, EAPs or IIR sites."

For the Millers, these statements are a punch in the gut, as they know their baby boy is running out of time.

"Some days are better than others. Some days he's happy go lucky and other days he goes into staring spells, and he won't respond to his name," said Rickey.

"We need it now, if we have to wait, it will be too late for Woodrow," said Denise.

The family continues to plead with FDA officials and are hopeful lawmakers could intervene and get children like Woodrow access to Adrabetadex.

Despite the results of the clinical trials cited by the company, many parents say their children are proof that this drug works.

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