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ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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March 7, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Azar:

Thank you for appearing before the Subcommittee on Health on February 15, 2018, to testify at the hearing entitled "Oversight of the Department of Health and Human Services."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on March 21, 2018. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

The Honorable Michael C. Burgess, M.D.

1. Mr. Secretary, the HHS budget proposal suggests requiring doctors who receive Federal funding and are enrolling in Medicare, Medicaid, or CHIP to use centralized CMS screening. Current regulations allow State Medicaid Agencies to rely on CMS screening, but doctors may still be subject to duplicative screening because of other screening programs (such as other state and Federal programs and managed care plans). I am interested in this idea, because some GAO and OIG work suggests states have struggled to successfully implement timely, efficient provider enrollment requirements. Could you please share your thoughts about ensuring this proposal would not just federalize the challenges and create a bigger headache for CMS who has also struggled?

2. The budget requests Congress clarify the authority for the Healthcare Fraud Prevention Partnership created under President Obama. If Congress were to provide this public-private partnership between CMS and health plans with explicit authority, the Partnership will be able to clearly define the rules and responsibilities of its members and expand the scope of allowable activities to address the full spectrum of fraud and abuse in the healthcare sector, particularly efforts to examine large public health issues that have fraud, waste, and abuse implications, such as addressing opioid misuse. I suspect this kind of idea would have strong bipartisan support in this Committee. So, would you commit to your staff getting us the specifics you think would help strengthen this program integrity effort in a timely manner?

3. Mr. Secretary, I would like to compliment your Department for taking steps to improve the ability of consumers to enroll in health insurance coverage through a private health insurance exchange. There seems to be continued redundancy which comes at the expense of American taxpayers. Could you please share your thoughts on what other positive steps HHS can take to improve the ability of consumers to get coverage under the current market?

4. Mr. Secretary, I concerned about the significant impact the application of the sequester on Medicare Part B drug payments, specifically those used in the treatment of cancer and other serious diseases. Couple years ago, I joined a letter with 123 bipartisan House members to CMS inquiring about their authority to apply the sequester to Part B drugs payments – as the reimbursement rate of those drugs (ASP+6) is already defined in statute. Yesterday, our Oversight and Investigations Subcommittee held a hearing entitled “Examining the Impact of Health Care Consolidation”. The application of the sequester is having a negatively impact on patients by fueling consolidation of their providers into more costlier settings, such as hospitals. Is this an issue we can continue to work on and where our offices can be engaged?

5. Mr. Secretary, Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) enacted broad reforms to the Medicare Clinical Laboratory Fee Schedule (CLFS), so that Medicare rates for clinical laboratory services would be reflective of the private market rates of all laboratories. The goal of CLFS reform is to create fair and accurate reimbursement so that the Medicare program realizes savings and that Medicare beneficiaries have sustainable and robust access to life-saving clinical laboratory diagnostic services. However, the Committee has heard significant concern from both stakeholders and Members of Congress that the data collected by the Centers for Medicare & Medicaid Services (CMS) does not accurately reflect private market prices of the full laboratory market of independent laboratories, hospital laboratories and physician office laboratories, and the CLFS rate reductions that began on January 1 of this year will threaten Medicare beneficiary access. Due to our concerns with PAMA implementation and artificially low reimbursement rates for laboratory tests, Energy & Commerce Committee has been working diligently with our counterparts on the House Ways & Means Committee and Senate Finance Committee to determine if legislative intervention is required. Staff from the three committees have made a bipartisan and bicameral request to CMS for technical assistance (TA) comments on potential legislative options to amend PAMA and ensure the intent of CLFS reform is realized. Do we have your commitment to engage with CMS and this Committee on our oversight of PAMA and possible legislation?

6. Mr. Secretary, the National Clinical Care Commission Act (PL 115-80) was enacted on November 2, 2017. The law establishes within the Department of HHS the National Clinical Care Commission that is tasked with evaluating and recommending solutions on how federal programs can better coordinate and support care for people with diabetes and related metabolic syndromes and disorders. Would you be able to provide a status on when the National Clinical Care Commission will be composed?

The Honorable Brett Guthrie

1. On January 19, 2017, the FDA issued a proposed rule on smokeless tobacco products. I understand that the Agency is currently reviewing the more than 10,000 comments to this proposed rule, including comments from the Department of Agriculture.

    a. How has your office incorporated USDA's economic analysis on the proposed rule? If the department has not already reviewed this report, will your commit to reviewing and giving full consideration to the report's findings as you move forward?

The Honorable John Shimkus

1. I want to alert you to something that will be coming to CMS in the near future that is important to my state and my constituents. The Illinois Hospital Assessment Program expires on June 30 and the State has been working with bi-partisan legislative leaders, and the hospital community on a new plan to update and modernize the program. Bi-

partisan legislation will be finalized soon in Springfield, and I look forward to working with you and CMS to ensure it is approved quickly. This program is critical to ensuring patient access to care in my district.

2. Mr. Secretary, last year each Agency established a Regulatory Reform Task Force and, in September, FDA sent out a request for information on regulations that hurt job creation, are ineffective or impose costs that exceed their associated benefits.

3. I have heard from employers in my state that the "Intentional Adulteration Rule" which seeks to protect the food supply from those who may intentionally attempt to cause harm to public health.

4. There is no higher priority for our nation's food company's than a safe food supply, but there is concern that the rule, as drafted, misses the mark. Would you consider speaking to your team about amending the rule to ensure the requirements will indeed do what are intended?

5. A variety of programs within the Department of Health and Human Services (HHS) have been an essential resource for antibiotic research and development (R&D) and additional efforts to combat antimicrobial resistance (AMR). Despite modest but important progress, the antibiotic pipeline remains very fragile. Many of the influenza deaths we're seeing this season are actually due to secondary bacterial infections like pneumonia, which are extremely difficult to treat due to antibiotic resistance. This would be far worse in a true pandemic. Are there additional tools or resources that would strengthen HHS's work to spur antibiotic R&D and combat AMR? What more could and should be done in this area?

6. Mr. Secretary, according to some estimates:

   - Annual Federal and state government smoking-caused Medicaid payments: $39.6 billion [Federal share: $22.6 billion per year. States' share: $17.0 billion]

   - Federal government smoking-caused Medicare expenditures each year: $45.0 billion

   - Other federal government tobacco-caused health care costs (e.g. through VA health care): $23.8 billion

   Do you agree with those numbers or do you have a better data?

7. Given the high cost to the federal government of smoking-related health care and the potential public health benefits to children who we hope never start smoking, can you describe more thoroughly FDA's plan and timetable to lower the amount of nicotine in cigarettes to minimally or non-addictive levels? Has FDA appropriately prioritized implementation of its plan?

The Honorable Cathy McMorris Rodgers

1. I have sponsored legislation in the past to address Medication Therapy Management (MTM) services that a licensed pharmacist can provide to a patient. As you know, patients who are not taking their medications as prescribed cost our healthcare system approximately $290 billion annually.

2. As Congress continues its focus on health care reform, do you see an opportunity to further promote MTM services, through legislation or a CMS regulatory pathway or a combination of both?

3. On November 16, 2017, CMS released the proposed rule entitled "Contract Year 2019, Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program," where CMS proposed to create a further incentive for plans to utilize MTM programs. Under current requirements, Part D plan sponsors and Medicare Advantage plans are required to meet a medical loss ratio of 85 percent, meaning the plan must not spend more than 15 percent on administrative functions. The goal is to incentivize plans to spend more on patient care and on items such as quality improving activities (QIA). There has been confusion as to whether the services provided in the Part D MTM program are considered an administrative function or a QIA. CMS is proposing to clarify that Part D MTM programs will fall under the QIA side of the formula.

4. Do you see this proposal as part of the final rule? Also, classifying MTM program to fall under the QIA side of the formula a first and complimentary step in advancing MTM?

5. The Centers for Medicare and Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (CMMI) October 3, 2016 announcement of the participants for the Part D Enhanced Medication Therapy Model is an opportunity to test additional incentives and flexibilities to Part D sponsors. I believe in better health outcomes for patients through proper medication adherence, at the same time we should achieve taxpayer savings, through reduced costs to the government. However, the design, limited geographical regions and duration of the Enhanced MTM Model are a concern and I believe the agency should reconsider aspects of the current model in order to attain more meaningful representation of retail pharmacy participation across the United States, where pharmacists are providing care and services to their patients.

6. Is there a possibility for CMS to expand the model in order to incorporate more retail pharmacy participation?

The Honorable Gus M. Bilirakis

1. Currently there isn't a clear standard for medication-assisted treatment (or MAT) prescribing, and we've heard reports of an increasing number of rogue actors offering MAT. In many cases these "pop up clinics" actively recruit vulnerable client populations and provide substandard services with minimal oversight. While we support consumer choice and market competition, we also want to balance this with consumer safeguards to ensure that this problem improves, not worsens, and that bad actors are not rewarded via federal dollars. Additionally, questions have been raised as to whether states are requiring evidence-based practices be used in the STR grant program. What is HHS doing to ensure rogue actors are not the recipient of federal dollars and evidence-based practices are being used so that funds expended go to providing the best possible treatment and recovery services?

2. Socio-economic status is one factor that drives health costs. We can see some of that data from Medicare Advantage Special Need Plans where they deal with the dual-eligible population. How can we better engage with these patient populations to achieve better outcomes?

3. The 21st Century Cures Act included additional enforcement and implementation authorities to ensure consumers can access the benefits afforded to them under the Mental Health Parity and Addiction Equity Act. Additionally, Congress directed the Agencies to release a parity compliance document, additional guidance on non-quantitative treatment limitations and disclosure and report on federal investigations within the previous 12 months by December of last year. Can you please advise the Committee on when these materials will be released?

4. Secretary Azar, the recently proposed Part D rule includes a request for information (RFI) on instituting point-of-sale rebates in the Medicare Part D program. In the RFI, CMS estimates that this proposal would increase monthly premiums for all Part D beneficiaries by up to 11 percent, representing $28.3 billion in increased premium costs over the next ten years. As you know, seniors are price-sensitive when shopping for Part D coverage, particularly when it comes to premiums, and I am concerned that a sudden 11 percent increase in monthly premiums could cause many seniors to forego prescription drug coverage.

    a. Have you examined the impact that such a dramatic increase in monthly premiums could have on seniors' enrollment in Medicare Part D?

    b. Will you model how these premium increases would affect enrollment before instituting such a major change?

    c. Will you go through the full rulemaking process before CMS institutes a change to POS rebates?

5. Puerto Rico has the highest Medicare Advantage penetration in the nation, with 98% of MA-eligible duals and 50% of dialysis patients in a Plan. Unfortunately, due to data anomalies in the reimbursement "formula," Puerto Rico MA programs are severely underwater, with the Island's rates at 43% below the US average, and 39% below the lowest state. The CMS reimbursement for Puerto Rico is even 26% below the US Virgin Islands. Payments for services to dialysis patients are equally 42% below Florida and 28% below the USVI. While I understand that the MA Plans have been in to see CMS and presented extensive data to improve the reimbursement, in its latest proposal for 2019 CMS proposed no meaningful changes to mitigate this harmful and persistent gap. Would you be willing to exercise your administrative discretion to find ways to meaningfully improve the MA programs in Puerto Rico?

6. The 21st Century Cures legislation signed into law in 2016 makes an important first step in addressing some regulatory hurdles for life-saving treatments by codifying a breakthrough pathway process at FDA to encourage more timely review of innovative medical technology. This provision had FDA's support. However, a similar effort is currently lacking within CMS to create a more efficient coverage and reimbursement process for FDA-approved breakthrough technologies. How will you improve the current process for getting breakthrough products covered in Medicare?

7. There is an interim final rule pending at OMB that would address some of the immediate needs of the home medical equipment industry under competitive bidding by maintaining the transition rates in the 21st Century Cures law. This will be a good first step to addressing some of the real crises in the home medical equipment community and addressing access needs for Medicare beneficiaries. Can you help free this rule at OMB and get it published?

The Honorable Billy Long

1. Secretary Azar, the ACA included a Medical Loss Ratio (MLR) provision that, as implemented in CMS regulations, counts agent and broker commissions as overhead. I'm concerned about the negative effects this has had on the marketplace. We all know how important competition is to a healthy marketplace. I think this should be exempt from the broader formula, and I believe HHS has the regulatory flexibility to make this change. Will you commit to looking into this with your general counsel and discussing ways we may be able to achieve this?

2. As you may know, I'm the sponsor of the HHS Cybersecurity Modernization Act, which would give HHS the ability to reorganize its cybersecurity offices and personnel to better reflect modern cyber threats. I believe the bill is especially important considering recent cyber incidents in the health care sector like WannaCry, NotPetya, and other ransomware and malware attacks.

3. What is HHS currently doing to ensure that both the Department and the health care sector are prepared for and addressing cyber threats? If you could include the roles of

ASPR as the Sector Specific Agency, and the Healthcare Cybersecurity Communications Integration Center in particular, I would appreciate it.

4. Is ASPR currently in charge of the Healthcare Cybersecurity Communications Integration Center? If not, will the H-CCIC be moved under ASPR in keeping with ASPR's role as the health care Sector Specific Agency?

5. Do you believe that HHS needs to do more to help both the Department and the health care sector better manage cyber threats? If so, what steps do you think the Department should take?

The Honorable Markwayne Mullin

Mr. Secretary – As you know, my home state of Oklahoma has been working with CMS for over a year to renew its Medicaid waiver. As part of that waiver, the state, in a budget neutral manner, since the 1990s has sought and has received permission from CMS to operate an arrangement that allowed for University of Oklahoma (OU) and Oklahoma State University (OSU) to treat Medicaid patients expanding access into rural areas, but also train future physicians of the state in needed specialties.

However, this Administration has taken steps to stop this arrangement in its tracks, putting in jeopardy not only services for patients in rural areas and specialties, but also the training of the next generation of physicians.

While the state and CMS have had good discussions lately on a solution going forward, I'm concerned that CMS will continue on its path to clawback $31 million paid to the state for services already provided. Would you please provide me an update, in writing, about the steps your department will take to ensure Oklahoma's medical schools are able to treat patients, as well as train future physicians? Specifically, I would like HHS and CMS to work together to find an acceptable path forward on the payments to the state to support the medical colleges for 2017 and 2018, but also work with the schools to find a long-term solution to this very important issue. Attached is further background on this issue. I respectfully request your attention to this very important matter and need your help to get to the bottom of this situation, and quickly.

The Honorable Frank Pallone, Jr.

ACA

Since the Affordable Care Act was first implemented, the uninsured rate steadily declined, year after year. From 2010 to 2016, 20 million Americans gained health insurance. Unfortunately, The Department has made it difficult for people to gain coverage in the health insurance exchanges, by drastically reducing funding for outreach and education activities, limiting the time for enrollment, and giving consumers less opportunities to make informed choices. These actions have made it much harder for Americans to access and afford the vital health insurance coverage they rely on. As a result, for the first time since the ACA was implemented, the uninsured rate actually increased. According to Gallup, 3 million more Americans were

uninsured in 2017 compared to 2016. It was also the largest single-year increase that has been observed since Gallup began collecting this data.

1. How does HHS plan to reverse this negative trend of insured rates?

2. Does HHS commit to working towards stabilizing the health insurance marketplaces? If so, what methods does HHS plan to take to improve the health insurance marketplaces?

The Administration has sabotaged the health insurance markets by cutting off cost-sharing reductions, reducing ACA marketplace enrollment periods and outreach, and allowing the sale of "junk" insurance plans that don't provide adequate healthcare coverage or financial protection for families. Many independent analysts, including CBO, estimated that premiums increased an average of 20% as a result of the decision to pull CSRs.

At the hearing, you expressed your interest in ensuring access to health care and that having health insurance is a key part of providing access. What steps is HHS taking to ensure that there is full implementation of the ACA?

Idaho health insurance market

At the hearing we discussed a recent letter that was sent to you and Administrator Verma regarding the state of Idaho's recent release of guidelines for their state health insurance marketplace that eviscerate critical consumer protections that are enshrined in the ACA. This would allow insurers in Idaho to deny individuals with pre-existing conditions health insurance coverage, deny pediatric vision and dental care coverage, increase health insurance costs for older Americans, and exclude coverage for maternity and newborn care. When questioned at the hearing about your understanding and response to Idaho's transgression of the ACA health insurance market consumer protections, you stated that you "would need to check under the 1332 waiver authority" and complete a "review for compliance with the legal obligations that we have in our statutes". Given the importance of this issue to working families in Idaho, we hope that you have prioritized this matter and conducted a thorough review of Idaho's guidelines.

1. Following your review, please explain if HHS and/or CMS believes that Idaho's actions are in full compliance with the Federal law and provide any documentation that provide the legal justification.

2. If you have concluded that any of the provisions in the Idaho guidelines are in violation of Federal law, what enforcement actions do you intend to take to hold the state of Idaho accountable?

3. If you have determined that Idaho's guidelines are in compliance with Federal law, please describe the review process you conducted Idaho's health insurance "state-based plans" that are to be sold to consumers.

4. In addition, please respond fully to the questions that were included in our letter sent on January 31, 2018 regarding Idaho's "state-based plans".

CMMI

4. The CMMI RFI states that, "CMS may publicly post the comments received, or a summary thereof." Does CMS plan to publish all the public comments that were submitted for the Centers for Medicare & Medicaid Services: Innovation Center New Direction, a summary of the public comments, or both? How many comments has the agency received to date?

5. Who at your agency decides whether public comments or a summary of the public comments will be published? What is the criteria by which the agency selects comments for publication?

6. If CMS plans to publish the public comments or a summary of the public comments for the CMMI RFI, when is publication expected? Please provide a copy of the summary of public comments.

7. Please provide a briefing on the process being utilized to determine CMMI's New Direction.

8. For the recently released RFI issued through ASPE on "Promoting Healthcare Choice and Competition across the United States," what plan does the agency have for review and publication of the public comments received in response to this RFI? Why was this RFI published only through ASPE and not on the Federal Register?

Medicaid Waivers

Transparency for the review and decisions on 1115 waivers must improve. It is the Committee's understanding that Section 1115 waivers have been approved without adequate time allowance for the public to comment with the benefit of the context of major changes to agency policy, such as work requirements. For instance, the Kentucky 1115 waiver was filed long before the Administration issued its guidance on work requirements; the public should have had the opportunity to comment on Kentucky's waiver with the knowledge and understanding of CMS' broad policy changes to the program. Instead, the Administration approved the Kentucky waiver just one day after issuing guidance for the program tying Medicaid to a work requirement.

9. In the instance of Kentucky and their waiver for work requirements, how was this waiver reviewed? Did CMS conduct an assessment of the number of individuals this would affect, who it would affect, and the implications it may have on the insured rates and health care outcomes of families in Kentucky?

10. How does HHS plan to improve the transparency of the 1115 waiver process?

11. What will HHS do to avoid conflicts exemplified by the Kentucky waiver approval and CMS guidance release in the future?

Currently, five states: Maine, Arizona, Utah, Wisconsin and Kansas, have applied for waivers from the Department of Health and Human Services to put a cap on how long Medicaid beneficiaries can receive health benefits. Additionally, 10 states have applied for work requirement waivers: Arizona, Arkansas, Indiana, Kansas, Kentucky, New Hampshire, North Carolina, Maine, Utah, and Wisconsin.

12. What process did HHS use to review these submitted waivers?

Medicaid cuts and the Opioid Epidemic

Medicaid covers 4 in 10 nonelderly adults with an opioid addiction, 80 percent of infants with neonatal abstinence syndrome (NAS), and is the largest insurer for children. At the hearing you agreed that access to preventative care services and making health care affordable is important. However, President Trump's 2019 budget proposes $1.4 trillion cut to Medicaid, more than 25 percent, over 10 years through block grants and per capita caps. These cuts would be devastating to our nation and limit access to preventative health care, mental health, and substance abuse treatment for millions of Americans.

13. Please describe how DHHS plans to commit to the opioid crisis and ensure health care access for preventative health and substance use disorders.

14. What resources will be available under President Trump's proposed budget for fiscal year 2019 for treating opioid use disorders, substance abuse disorders, and mental or behavioral health conditions? Provide a list of any resources that will no longer be available and an explanation of why these resources will be cut.

15. For any resource loss due to President Trump's proposed budget for fiscal year 2019, provide corresponding estimates on the number and demographics of individuals that will be affected.

Public Health

The Centers for Disease Control and Prevention, the nation's public health and prevention agency, actually saw its core programs cut by more than $1 billion overall, when not adjusting for the $175 million additional opioid allocation. While some of those cuts come from eliminating or transferring programs from CDC, others such as the more than 10 percent cut in funding for chronic disease prevention and health promotion, would harm our ability to protect the public from costly, preventable disease. At the hearing, you stated that investments were being made in chronic disease and prevention, through the immunization program and emerging infectious and zoonotic diseases. You also stated that the $1 billion in cuts was mostly the result of "the transfer of the leadership and supervision and budget for the strategic national stockpile."

16. Please explain how the Administration believes that cuts to CDC will help the Agency better fulfill its mission of being the nation's health protection agency, to protect America from health and safety threats, both foreign and domestic?

Restoring Integrity, Accountability, and Transparency at HHS

In the last year, there have been a number of ethical lapses that have plagued HHS and its operating divisions over the last year. Those lapses have raised serious concerns regarding whether the Trump Administration is truly committed to working in the public's best interest.

The former Secretary Tom Price, was forced to step down after the public learned that he had taken 24 flights on private charter planes at a cost of more than $300,000 in just his first five months of service. According to Politico, between the months of May and September 2017, Secretary Price's travel cost taxpayers more than $1 million.

17. Will HHS be conducting a thorough review to determine whether any other instances of federal travel regulations were violated at HHS and each of its divisions?

18. Who at HHS approved and processed former Secretary Price's flights as well as instances where federal travel regulations may have been violated?

19. What measures is HHS taking to ensure full compliance with federal travel regulations and to prevent the waste of taxpayer dollars on chartered flights when more cost-effective modes of travel are available?

In January, former CDC Director Brenda Fitzgerald, the country's top public health official, resigned over investments she made in tobacco companies one month into her tenure as head of CDC.

20. What steps are you taking to determine whether other HHS officials have similar conflicts of interest that prevent them from serving the public without undue influence?

21. What measures are you taking to ensure full compliance by HHS officials with applicable federal ethical regulations, policies, and procedures pertaining to conflicts of interests?

22. How will you ensure that all HHS political appointees disclose any conflicts of interests, in particular those that might seriously limit their ability to do their jobs, to HHS ethics office?

Freedom of Choice

In January of this year, HHS announced that it would be rescinding guidance issued in 2016 by CMS which clarified existing Medicaid law concerning the freedom of choice provision. This 2016 guidance noted that states are not permitted to deny Medicaid funds to family planning

providers solely because they separately offer abortion services. However, in rescinding this guidance, and doubling down by proposing to prohibit these providers from receiving Medicaid funds in the budget, HHS is signaling its support for restricting access to family planning and other preventive health services.

23. Does HHS intend to allow women who obtain care through Medicaid to access family planning services from their provider of choice?

24. How will HHS ensure that Medicaid beneficiaries maintain access to comprehensive family planning services if certain reproductive health care providers were prohibited from the Medicaid program?

Title X Family Planning

A paragraph in the HHS budget-in-brief notes that the budget prohibits certain abortion providers from receiving Title X funds. HHS has not provided any details on this proposal beyond this paragraph. Providers are only able to use Title X funds to provide affordable contraceptive care, and not for abortion services, and the Title X program has been credited for playing a key role in lowering the unintended pregnancy rate.

25. How does HHS intend to ensure that patients who receive care through Title X will maintain access to the broad range of reproductive and preventive health services that are currently provided through the program?

Following a significant delay, on February 23, 2018, HHS released the Funding Opportunity Announcement (FOA) for 2018 for the Title X Family Planning Service Grants. Title X provides critical grants to public and nonprofit agencies for family planning services, research and training.

26. What was the reason for the significant delay in announcing the 2018 Funding Opportunity Announcement for the Title X program?

27. Prior FOAs explicitly stated that family planning services include, "clinical family planning and related preventative health services." Please explain the reason HHS excludes this language from the 2018 FOA.

28. The 2018 FOA removed the requirement for providers granted Title X funding to follow Providing Quality Family Planning Services: Recommendations of the CDC and the US Office of Population Affairs (QFP). The QFP is the nationally recognized clinical standards for what defines quality for family planning. Please explain why references to the QFP were not included in the 2018 FOA.

29. Why does HHS feel that family planning care would be "optimally" provided in comprehensive primary care settings instead of sites that focus on family planning and sexual health care?

30. Does HHS plan to issue new proposed regulations in relation to the Title X family planning program?

Drug Pricing – 180 Day Exclusivity

The President's budget includes a proposal intended "to give the Food and Drug Administration (FDA) greater ability to bring generics to market faster by incentivizing more competition among generic manufacturers." It describes the proposal as allowing FDA "to tentatively approve a subsequent generic application, which would start the 180-day exclusivity clock," "when a first-to-file generic application is not yet approved due to deficiencies." Can you provide more detail about this proposal? Specifically:

31. Please describe specific examples of "deficiencies" that this provision is intended to address. How many times has FDA encountered this situation within the past 10 years? Please also provide the number of tentative approvals within the past 10 years obtained by first applicants that did not obtain final approval and within what timeframe, and the reasons for which such final approval was not obtained in a timely way.

32. As you know, 180-day exclusivity has provided a powerful incentive for generic competition that today saves taxpayers and patients more than $250 billion per year. Please explain how the proposal would not undermine the value of 180-day exclusivity, particularly given the unknown and unexpected timing of a subsequent applicant's tentative approval that could trigger a first applicant's exclusivity.

33. How does this proposal safeguard manufacturers who have received a tentative approval and are in good faith working towards final approval?

Drug Pricing – REMS Abuse

During your confirmation process, you spoke about the need to "fight gaming in the system," to take action to lower prescription drug prices, and you committed to working with Commissioner Gottlieb on solutions to end the abuse of FDA's safety protocols and the use of specialty pharmacies to limit access to drug samples. However, in the fiscal year (FY) 2019 budget, the administration does not include any proposals to end these abuses.

34. Two bipartisan proposals – the FAST Generics Act and the CREATES Act – are market-based solutions to increase competition and lower prescription drug prices. Over 60 organizations now support these solutions and CBO estimates the CREATES Act would generate savings of $3.8 billion. Commissioner Gottlieb and Janet Woodcock, M.D., as well as the Federal Trade Commission, have indicated the FDA does not have the authority to compel brand companies to provide samples to generic manufacturers and thus Congressional action is necessary. Will you support the FAST Generics Act and the CREATES Act?

35. The FY19 budget includes a range of policies intended to lower prescription drug costs. However, none of the policies would impact the list price of brand biologics and drugs. With brand biologics accounting for nearly 50 percent of all prescription drug spending, and continued double-digit annual price increases for these blockbuster drugs, why does the budget fail to include any proposals to address the list price of brand drugs?

36. One of the concerns expressed by President Trump and others in the administration is the high cost of prescription drugs in the United States compared to other countries. The Commonwealth Fund, for example, noted last year that "prices for many blockbuster drugs are markedly higher in the U.S." than the rest of the world with U.S. spending on pharmaceuticals exceeding $1,000 per person and prices 30 to 190 percent higher than in nine other countries. In your experience, including your previous position at Eli Lilly, have price increases of brand drugs in foreign countries ever allowed the company to lower drug prices for its products in the U.S.? If so, can you provide specific examples of when this has occurred?

WTC Health Program

The National Institute of Occupational Safety and Health (NIOSH) has been at the forefront on protecting the health and safety of the survivors of the World Trade Center (WTC) attack as well as the brave men and women who responded. Their leadership dates back to the fall of 2001 when Congress first appropriated funding to HHS to screen responders for respiratory complaints. NIOSH's efforts have been invaluable to ensuring that WTC survivors and responders receive the health services they need. NIOSH leadership continues today as Dr. John Howard serves as the Director of the National Institute for Occupational Safety and Health and the Administrator of the World Trade Center Health Program within the Centers for Disease Control and Prevention (CDC). The FY 2019 Trump Budget proposes moving the National Institute on Occupational Safety and Health to the National Institutes of Health (NIH) while leaving the WTC Health Program at CDC.

37. What is the effect on the WTC Health Program of removing that program from long-term leadership of NIOSH? What analysis has HHS completed to understand those effects? Did HHS seek input from the 9/11 health community to understand those effects?

38. As mentioned above, the Director of NIOSH also serves as the Administrator of the WTC Health Program. Please describe how the leadership of the WTC Health Program would be handled under the Budget proposal? Would the Director of NIOSH remain the Administrator of the WTC Health Program?

39. The WTC Health Program relies on the expertise of NIOSH staff, and in fact, in some instances uses shared staff positions to fulfill its mission. Under the President's proposal, how would HHS ensure that WTC Health Program maintains the expertise and staffing necessary to meet the needs of 9/11 responders and survivors?

The Honorable Eliot L. Engel

Last month, the Wall Street Journal reported that the Centers for Diseases Control plans to significantly scale back its work to prevent, detect and respond to global infectious disease outbreaks in nearly 40 countries when funding for the Global Health Security Agenda runs out in 2019. After that, CDC's global health security work will be limited to just 10 countries. The FY19 budget proposes $59 million to support the continuation of CDC's Global Health Security Agenda activities. With that funding, will the CDC still need to focus only on 10 countries?

The Honorable Janice D. Schakowsky

I would also like to ask about reports that high ranking officials within HHS and CMS coordinated with the anti-abortion organization "Alliance Defending Freedom", one that has been designated a hate group by the Southern Poverty Law Center, before the Administration's January 19th announcement that it was rescinding critical Medicaid guidance concerning where beneficiaries can receive family planning and reproductive health care.

I'm concerned about who is calling the shots at HHS. Coordinating with right-wing ideological organizations raises serious ethical questions. It also calls into question the legitimacy of any policy decisions by Trump's HHS.

1. Are there other occasions when non-HHS employees have drafted HHS guidance documents, regulations, or other written proposals? Or if HHS officials have sought input on policy decisions from ideologically conservative organizations outside of the appropriate notice and comment process?

2. Can you commit that you will take steps to ensure that HHS officials are not coordinating with biased ideological organizations to further specific policy proposals in the future

The Honorable G. K. Butterfield

1. According to a recent FDA publication, "Expanded Access of Investigational Drugs: the experience of the center of drug evaluation and research over a 10-year period," the FDA review of expanded-access requests includes knowledge of the totality of data and information that the commercial sponsor has submitted to the FDA for the development program, including data (e.g., safety/toxicity data, dosing considerations) that may not be publicly available. In addition, it states, "the FDA can recommend revisions to the treating physician's desired treatment plan to better protect the patient's safety." Would you agree that FDA plays a critical role in evaluating a favorable benefit-risk profile and assuring patient safety?

2. According to a paper by the FDA, "How Often Are Drugs Made Available Under the Food and Drug Administration's Expanded Access Process Approved?", the mean response time for non-emergency single patient INDs is four (4) days. Moreover, overall,

98% of individual patient Expanded Access requests were allowed to proceed. Would it be reasonable to conclude that the current system is operating efficiently?

The Honorable Doris O. Matsui

Rare Diseases

I'd also like to talk about patient-focused drug development and inclusion of real-world evidence. These provisions are not necessarily specific to rare disease patients, but I think they are especially useful for rare diseases as they provide additional opportunities to collect information about treatments.

1. Can you elaborate on FDA's work on patient-focused drug development? Where are we in the implementation of patient engagement staff and the inclusion of patient experience data in the approval process?

2. Can you also provide a more in-depth update on FDA establishing a new program to evaluate the potential use of real world evidence?

This will also be particularly helpful for those with rare diseases as real world evidence is sometimes all the evidence that we have for those patients.

3. How can NIH's Precision Medicine initiative benefit rare disease patients?

Drug Pricing – Combination Products

Last year, we were all shocked by the outrageous price increases in the EpiPen, a branded product where the actual drug (epinephrine) is cheap and common, but the auto injector device is unique to the company.

One way to prevent skyrocketing prices on products like these is to ensure adequate competition. The Cures provision to streamline the combination products approval process is intended to do that.

4. Has the Office of Combination Products been stood up and what assistance has been provided thus far or plans to be provided?

5. Do you agree that a streamlined process will enhance the potential for competition of combination products in the market?

Pediatric Inclusion in Research
Another priority in the 21st Century Cures Act has been to ensure that historically underrepresented populations – including minorities, women, and children – are included in medical research.

Children's medical research has long been a priority for me. As you know, we originally created the National Children's Study to look at long-term environmental impacts on children's health and development. NIH is currently following through on that idea with the Environmental Influences on Child Health Outcomes, or ECHO, Project. I look forward to continuing to work with NIH to ensure that that project meets the goals of understanding the effects of environmental exposures on child health and development.

In Cures, we included Sections 2071 and 2072 to promote pediatric research and inclusion of children in NIH research by creating national and global pediatric research networks.

6. Can you discuss NIH's efforts in this area and how the provisions in Cures have helped move things forward?

Mental Health

One area of research that I believe really has a long way to go and has great potential is research on the brain. We just don't know enough about how it works and how diseases of the brain manifest themselves.

Diseases of the brain are some of the most prevalent and impactful in our society. One in five people is affected by a mental illness and over 5 million Americans are diagnosed with Alzheimer's every year, including 630,000 Californians. The impact of these diseases are only going to grow as our population ages and as we face mental illnesses head on rather than pushing them to the shadows.

The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative at NIH intends to get at this problem – the lack of understanding of the human brain. BRAIN is helping researchers seeking new ways to treat, cure and prevent brain disorders.

7. Can you elaborate on the BRAIN Initiative and share any examples of success thus far? Are there any projects with great potential that you are excited about? What can we expect in the future and how can we ensure that the research from the BRAIN Initiative is translated into medical practice for patients?

Encouraging Innovation

The 21st Century Cures Act includes language that permits manufacturers of medical devices whose products have been approved for use by the European Medicines Agency, but denied or not yet reviewed by the FDA, to request a peer review of that data by a panel appointed by the FDA and paid for by the device manufacturer.

8. Would you support policy that would allow similar treatment of pharmaceutical products?

The Honorable Kurt Schrader

The Campaign for Tobacco Free Kids estimates that:

- Annual Federal and state government smoking-caused Medicaid payments: $39.6 billion [Federal share: $22.6 billion per year. States' share: $17.0 billion]

- Federal government smoking-caused Medicare expenditures each year: $45.0 billion

- Other federal government tobacco-caused health care costs (e.g. through VA health care): $23.8 billion

Given these numbers, I'm encouraged by the fact that the FDA has stated a goal to "enable greater use of safe and effective options to help those who are addicted to nicotine get the help they need to quit combustible cigarettes altogether." FDA's plan to lower the amount of nicotine in cigarettes to minimally or non-addictive levels is an important part of achieving that goal. Given the potential public health benefits to children who we hope never start smoking and to adults who want to quit, shouldn't this be a faster-moving priority?

The Honorable Joseph P. Kennedy, III

1. The Comprehensive Addiction and Recovery Act (CARA), P.L. 114-198, included provisions requiring HHS to establish an inter-agency task force to identify, review, and issue best practices on pain management within two years. While the Pain Management Best Practices Inter-Agency Task Force created in CARA does not have rule-making authority and cannot supplant existing CDC's 2016 Guidelines for Prescribing Opioids for Chronic Pain, it can supplement CDC's invaluable work. Can you provide me with an update on the status of the Inter-Agency Task Force and whether or not it has convened any meetings to date?

2. The 21st Century Cures Act, P.L. 114-255, includes provisions requiring HHS to enhance compliance with mental health parity laws. While HHS missed the June deadline for holding a public listening session, the law includes several other critical deadlines. Please provide a status update for each of the responsibilities assigned to HHS and listed in Section 13001 of the 21st Century Cures Act. Specifically, has the Department taken any measures to issue additional guidance to health insurance plans regarding their obligations under existing mental health parity laws; has the Department solicited public input and finalized the Task Force action plan; and has the Department issued a compliance program guidance document, including illustrative examples of previous findings of compliance and non-compliance? For all deadlines that HHS has missed, when will the Department fulfill the requirements under Section 13001?

3. It is my understanding that as recently as 2016 the Department's Office of Inspector General has investigated Universal Health Services (UHS) for a variety violations at their numerous mental and behavioral inpatient facilities. Please provide a status of all investigations into UHS that HHS has conducted and is conducting. Additionally, please provide information regarding any fraudulent reimbursements that UHS or any of its affiliate facilities billed Medicare or Medicaid. Specifically, detail how many instances of fraudulent billing occurred, over what period of time, involving which facilities, and for how much money.

The Honorable Anna G. Eshoo

ACA Sabotage and Contraception Coverage Guarantee

Contraception coverage was a critical aspect of the Affordable Care Act's (ACA) preventive health goal. In October 2017, HHS announced two interim final rules (IFRs) which significantly broadened the ability for employers to seek exemptions to the ACA's contraceptive coverage guarantee. Members of this Committee wrote to HHS in October asking a series of questions regarding the Department's decision to issue interim final rules expanding the exemption for contraception coverage. We have yet to receive a response to that letter.

1. Do you believe that health insurance coverage for contraception and related preventive services help to ensure full and equal health coverage for women?

2. How will HHS ensure contraception coverage for women who have lost coverage through their employer or university as a result of these IFRs?

3. Why did HHS choose to finalize these rules effective immediately, and not subject the rules to the APA-required notice and comment period?

4. What steps is HHS taking to ensure more women have access to the full-range of FDA approved contraceptive methods?

5. Do you commit to ensuring HHS continues to implement the HRSA preventive services guidelines as they relate to contraception?

Medicaid and Mental Health Services

Your agency purports to support increasing mental health treatment for the nearly 10 million Americans with serious mental illness. The President's budget creates new programs and centers to address mental health and substance abuse. The same budget slashes $1.4 billion from Medicaid, our nation's primary source for mental health and substance abuse treatment coverage.

6. How will people enrolled in Medicaid access mental health services if and when they lose their health insurance coverage because of the budget proposals to cut and cap Medicaid?

7. Have you met with a Medicaid recipient?

Centers for Disease Control and infectious disease programs

I'm working with my colleague Rep. Susan Brooks to reauthorize the Pandemic and All-Hazards Preparedness Act so I'm familiar with the threats that emerging infectious diseases pose. These threats are not going away any time soon, the risk posed by these diseases is only increasing.

How does your agency plan to protect against the growing threat of emerging infectious diseases if the emerging and zoonotic infectious diseases program, which is responsible for detecting, controlling and preventing these threats, is cut by $60 million?

Biodefense

The FY18 budget addendum includes moving funding for Project BioShield from the current annual appropriations process to advanced appropriations and provides additional funding for this program.

Is Project BioShield currently limited in its ability to make investments in promising products because it is appropriated annually?

How will advanced appropriations promote and enhance the work that Project BioShield currently does?

The Honorable Diana DeGette

On December 6, 2017, Representative Tom Reed and I sent a letter asking HHS to apprise the Diabetes Caucus of steps CMS and FDA are taking to ensure that seniors with diabetes receive diabetes testing supplies that work as intended. That request was prompted by a June 2017 study that evaluated the accuracy of some of the most commonly used personal-use blood glucose testing systems, including those most commonly furnished to Medicare beneficiaries through the Medicare Competitive Bidding National Mail Order program, that found that only six of eighteen systems tested met the study's accuracy standard. On January 24, 2018, Acting Secretary Hargan responded with a list of steps FDA has taken and intends to take with respect to product review and monitoring, but with respect to CMS, the letter said only that CMS has been monitoring health outcomes data for beneficiaries receiving tests strips, and that "to date [CMS] has not detected any negative trends." Outcomes data may be a prudent way to identify adverse beneficiary outcomes, but according to the study, Medicare is paying for items that fail to meet basic performance standards, and more than 61 percent of the strips furnished to Medicare beneficiaries during the period October through December 2016 failed accuracy standards under this study. Do you believe that CMS also has a responsibility to ensure that the items it pays for function as intended, and that CMS should undertake additional steps to ensure that it is managing the public's Trust Fund consistent with its fiduciary responsibility?

The Honorable Peter Welch

Secretary Azar, I want to turn for a moment to one of the factors driving high drug costs and that is abuse of our regulatory system by some brand manufacturers to extend their patent life or to further delay competition. One such problem I have been focused on trying to fix is the abuse of REMS programs, which were put in place to ensure the safe use of certain drugs, but are being used by brand manufacturers to delay the ability of generic manufacturers to purchase samples of drugs needed to conduct studies to support FDA approval. Commissioner Gottlieb has recognized this gaming and has called on brand manufacturers to "end the shenanigans."

The tactic of using REMS to delay competition has had a very real impact on patients. Take the recent story of Pam Holt, who has been using Revlimid to treat her multiple myeloma. Her co-pay is $640 a month, and despite the fact that Revlimid has been available since 2005 there is still not a generic on the market. David Mitchell, founder of Patients for Affordable Drugs, who also has had to take Revlimid to treat his cancer, has testified before Congress that the lack of a generic on the market is due to the manufacturer repeatedly denying generic manufacturers samples under the guise of a REMS program.

And if you don't believe the patients, Dr. Woodcock has confirmed herself that there have been around 150 inquiries from generic manufacturers to FDA reporting about difficulties they have had in obtaining samples from brands for bioequivalence testing.

1. Do you agree that we need more competition in the pharmaceutical marketplace and that we must address the gaming of our regulatory system by brand companies that delays generic competition?

2. There have been two bipartisan proposals to address REMS abuse introduced this Congress – the FAST Generics Act and the CREATES Act. Will you work with me on legislation to help end REMS abuse and to facilitate access to samples?