

Questions for the Record

Oversight of the Department of Health and Human Services

Health and Human Services Secretary Alex M. Azar II

February 15, 2018

United States House Committee on Energy and Commerce

Representative Shimkus

Question: 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.

Response: CMS looks forward to reviewing information submitted by the state and working with you however appropriate.

Question: 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.

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.

There is no higher priority for our nation’s food companies 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?

Response: I know that there has been continuing interest in contaminating the food supply by those who wish to do harm to Americans. While this risk is low, it is not zero. As with other forms of terrorism, we must be prepared for this possibility. Many companies have taken steps to protect their products from intentional adulteration. The Intentional Adulteration rule, which is a requirement of the FDA Food Safety Modernization Act, is designed to build upon those efforts.

We have heard concerns about both the cost and flexibility of the Intentional Adulteration rule, particularly around vulnerability assessments. FDA has been working closely with industry on addressing those concerns where appropriate. FDA is also working on a guidance document to help clarify expectations for industry, to identify options for implementing the rule, and to address many of the cost and flexibility concerns that industry has expressed. We anticipate this draft guidance document will be issued soon.

We believe there are some misconceptions about the requirements of the Intentional Adulteration rule. We are committed to an ongoing dialogue with industry to work toward a common understanding of expectations for implementation of the Intentional Adulteration rule, including provisions relating to vulnerability assessments. FDA has collaborated with industry, academia, and government partners on food defense vulnerability assessments for more than a decade, and will continue to do so.

Question: 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?

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?

Response: Protecting children from the harms of tobacco use is indeed a high priority. Because almost 90 percent of adult smokers started smoking before the age of 18 and nearly 2,500 youth in the United States smoke their first cigarette every day, lowering nicotine levels could decrease the likelihood that future generations become addicted to cigarettes and allow more currently addicted smokers to quit more easily.

The Federal Food, Drug, and Cosmetic (FD&C) Act provides FDA with the authority to establish tobacco product standards. This includes the authority to adopt a tobacco product standard if the Agency finds that it is appropriate for the protection of the public health. In making such a finding, the Agency must consider scientific evidence concerning: (1) The risks and benefits of the proposed standard to the population as a whole, including users and nonusers of tobacco products; (2) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (3) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

To begin the process, FDA has initiated a public dialogue about lowering nicotine levels in combustible cigarettes to minimally or non-addictive levels. FDA has issued an advanced notice of proposed rulemaking (ANPRM) to obtain information regarding the issues FDA would need to address in a tobacco product standard regulation to regulate nicotine levels in combustible cigarettes and render them minimally or non-addictive using the best available science to determine a level that is appropriate for the protection of the public health. The public docket for this ANPRM will be open for ninety days, and comments must be submitted on or before June 14, 2018, via regulations.gov. Reviewing the science and hearing from stakeholders will help FDA form the basis for regulatory action.

If FDA determines that a rule establishing a maximum nicotine level is appropriate for the protection of the public health, among the next steps would be for FDA to issue a proposed rule and obtain public comment. Then, after consideration of comments from stakeholders, FDA could publish a final rule establishing a maximum nicotine level in cigarettes.

Question: 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?

Response: The Department of Health and Human Services (HHS) is an active participant in implementing the National Strategy for Combating Antibiotic-Resistant Bacteria (CARB).

HHS is creating important new tools and collaborations to understand the mechanisms of antimicrobial resistance and facilitate the development of diagnostics, vaccines, and therapeutics to address antibiotic-resistant bacteria.

NIH, CDC, and FDA are collaborating to develop the National Database of Resistant Pathogens. This Database will serve as a global repository for genomic data on drug-resistant pathogens. The National Institute of Allergy and Infectious Diseases (NIAID) at the NIH is sequencing high-priority reference strains for the Database to facilitate research on drug resistance mechanisms, and to advance the development of new diagnostics, therapeutics, vaccines, and other antimicrobial strategies. NIH scientists also are working with colleagues from CDC and other institutions to improve our understanding of gram-negative bacteria responsible for bloodstream infections that are among the most deadly and difficult to treat. In addition, NIAID supports the Antibacterial Resistance Leadership Group, which oversees clinical research to reduce the public health threat of antibacterial resistance.

NIH, through NIAID, is partnering with BARDA on multiple efforts to enhance the pipeline of antimicrobial products that could be used to diagnose, treat, or prevent antimicrobial-resistant infections. NIH and BARDA participate in the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator, or CARB-X. CARB-X is an international public-private partnership for the early discovery and development of novel diagnostics, antibiotics, and vaccines that can be used to address the problem of antibiotic resistance. NIAID provides preclinical services and technical support to CARB-X awardees. NIH also has partnered with BARDA to launch the Antimicrobial Resistance Diagnostic Challenge competition to solicit innovative, rapid, point-of-need in vitro diagnostic tests to combat the emergence and spread of drug-resistant pathogens. CDC and FDA are providing additional technical and regulatory expertise for the Challenge. The Challenge competition may award up to \$20 million in prizes. Final awards following the three phases of the Challenge are expected in 2020.

Representative Burgess

Question: 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?

Response: As you note, the budget proposes requiring providers who receive Federal funding and who are enrolling in Medicare, Medicaid, or CHIP to use centralized CMS screening as necessary under Federal law. Regulations currently allow State Medicaid Agencies to rely on CMS screening, but providers are still subject to duplicative screening in many instances as multiple state and Federal programs and managed care plans may screen a single provider.

This proposal significantly reduces the administrative cost and burden associated with provider screening for Medicare Administrative Contractors, Medicare Advantage plans, State Medicaid Agencies, and Medicaid Managed Care plans and limits their exposure to making improper payments, especially for states that may not have the resources to fully comply with existing screening requirements, such as fingerprint-based criminal background checks. We note that screening is not equivalent to enrollment; however, CMS would provide all federally required screenings necessary for enrollment eligibility.

This proposal utilizes already established centralized screening procedures to bring consistency and accuracy to fraud, waste and abuse prevention across all federally funded healthcare programs. CMS has the infrastructure in place to efficiently and effectively conduct all federally mandated screening requirements. For example, CMS has implemented the Advanced Provider Screening (APS) system, which has the capability to continuously monitor all providers that receive Federal direct/indirect funding for licensure status, criminal history, death master file, and OIG exclusions in an automated manner. Federally funded healthcare programs would also be able to leverage CMS's existing fingerprint and site visit verification operations. Screening information would be easily accessible via the Provider Enrollment, Chain, and Ownership System (PECOS), CMS's centralized repository of provider screening and enrollment information. State Medicaid Agencies will retain flexibility to apply additional screening requirements but not to duplicate CMS screening.

Question: 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?

Response: HHS staff would be happy to work with your staff to provide additional information on this proposal. Currently, the Healthcare Fraud Prevention Partnership operates under the authority established for the Health Care Fraud and Abuse Control Program, which allows for data sharing to address fraud and abuse in health insurance. By providing 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, such as efforts to examine large public health issues that have fraud, waste, and abuse implications, such as addressing opioid misuse.

Question: Mr. Secretary, I'm 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 drug 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?

Response: I am happy to work with your office to learn more about this issue. HHS is committed to enacting reforms to ensure our healthcare programs work for the American people, provide Americans with access to care that meets their needs, increase options for patients and providers, and build financial stability and responsibility.

Question: 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?

Response: We are committed to accurate implementation of PAMA. In the Medicare Physician Fee Schedule proposed rule for calendar year 2018 (82 FR 34089), CMS solicited comments to better understand applicable laboratories' experiences with the data reporting, data collection, and other compliance requirements for the first data collection and reporting periods in order to inform us of potential refinements to the private payor rate-based CLFS for future data collection and reporting periods. In response to the solicitation, we received approximately 40 comments with specific recommendations such as improving the accessibility of the CMS data reporting system by removing certain security measures and changing the requirement that applicable laboratories must report data from claims that require manual remittance processes (82 FR 53181). CMS will consider the comments for potential future rulemaking. I understand that my staff have been in touch with the Committee staff to offer technical assistance on legislative options that you may be considering.

Question: 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?

Response: The status quo is not working for millions of Americans – whether it is those who are in the insurance market or those who have been left out of it. I look forward to continuing to work to create a health insurance system that is more affordable and responsive to the needs of individuals and their families, so that we have a healthcare system that is more affordable and accessible, where they can choose the type of insurance coverage that works best for them, including association health plans and the expanded options for short-term limited-duration insurance.

Short-term, limited-duration insurance plans are flexible, adaptable insurance products that can be particularly useful for those entering the job market, those transitioning between jobs and other

forms of insurance, or who are otherwise priced out of the unaffordable ACA insurance markets. Americans need more insurance options, and they need less Federal micromanagement of their insurance options.

Question: 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?

Response: We look forward to implementing the National Clinical Care Commission Act and setting up this Commission. The National Clinical Care Commission (NCCC) will ideally be composed by late spring or early summer. The Department looks forward to working with the many stakeholders engaged in these issues.

Representative McMorris-Rodgers

Question: 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.

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?

Response: Thank you Representative McMorris-Rodgers for raising this important issue. I agree that MTM services are a crucial tool we have available to help fight the opioid scourge. In 2017, CMS began testing the Part D Enhanced Medication Therapy Management (Enhanced MTM) Model, in which stand-alone basic Prescription Drug Plans (PDPs) in selected regions can offer innovative MTM programs, aimed at improving the quality of care while also reducing costs. CMS and accepted participants are testing changes to the Part D program that would achieve better alignment of PDP sponsor and government financial interests, while also creating incentives for robust investment and developing innovative MTM targeting and interventions. The objectives for this model are for stand-alone basic PDP sponsors to learn how to “right-size” their investment in MTM services and identify and implement innovative strategies to optimize medication use, improve care coordination, and strengthen healthcare system linkages.

Evidence suggests that the MTM services currently offered by Part D plans fall short of their potential to improve quality and reduce unnecessary medical expenditures, most likely due to misaligned financial incentives and regulatory constraints. Competitive market dynamics and Part D program requirements and metrics may incentivize investment in these activities only at a level necessary to meet the minimum compliance standards. Currently, Part D statutory and regulatory MTM provisions require uniform service offerings to enrollees who meet the plan’s program criteria, based on numbers of medications, and chronic conditions and expected annual prescription drug costs. The result is that Part D MTM programs may not include the level of resources nor the type of activities that could have the greatest positive effect on beneficiary outcomes. This model tests the impact of granting stand-alone basic PDP sponsors a limited waiver of existing MTM, benefit uniformity, and other related regulatory and statutory requirements to encourage Part D plans to offer more targeted and effective MTM services.

CMS is using an independent contractor to conduct an evaluation of this model and we look forward to the evaluator’s findings.

Question: 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.

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?

Response: CMS is reviewing the comments received on the proposed rule, and will consider all feedback as we finalize policies for inclusion in the final rule.

Addendum: Under the final rule,¹ CMS clarified that qualified MTM programs offered by Medicare Part D plans finalized on April 16, 2018, are allowed to be included as QIA in the calculation of the Medicare medical loss ratio (MLR). We believe this will encourage sponsors to ensure that MTM is better utilized.

Question: 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.

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

Response: That said, the provision of Enhanced MTM items or services may not be tied to use of specific network pharmacies for dispensing of Part D drugs. The model does not waive Part D network access requirements or any other Part D requirement not specifically listed in the Enhanced MTM Request for Applications. For the purposes of this project, CMS has indicated that a successful participant in this model will design an MTM program that effectively engages enrollees at risk for medication-related issues “where they are” as opposed to requiring the enrollee to come to the plan or plan preferred providers for assistance in overcoming a barrier to improved medication use.

¹ <https://www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare>

Representative Guthrie

Question: 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?

Response: FDA received almost 8,000 comments on the notice of proposed rulemaking on smokeless tobacco products and is currently reviewing and carefully evaluating all comments, including the Department of Agriculture's comment, to determine appropriate next steps. As always, we will give full consideration to the comments provided to us by our counterparts in the administration and from industry, stakeholders, and elected representatives.

Representative Bilirakis

Question: 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?

Response: The Department shares your concern about the impact of socioeconomic factors on healthcare costs and patient outcomes, and is committed to working with stakeholders to address these important issues. There is growing recognition that social risk factors – such as income, education, race and ethnicity, employment, community resources, and social support – play a major role in health, and significant gaps remain in health and in life expectancy based on income, race, ethnicity, and community environment. As you know, the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 (P.L. 113-185) required the Secretary to conduct research on issues related to socioeconomic status (SES) in Medicare's value-based payment programs. As required by the Act, in December 2016 the Assistant Secretary for Planning and Evaluation (ASPE) published a Report to Congress that provided a study examining the effect of individuals' social risk factors on quality measures, resource use, and other measures under the Medicare program, as well as analyses of the impact of Medicare's current value-based payment programs on providers serving socially at-risk beneficiaries and simulations of potential policy options to address these issues. In addition, in Medicare Advantage, CMS implemented an interim response to address the within-contract disparity in performance associated with a contract's percentages of beneficiaries with low income subsidy and dual eligible (LIS/DE) and disability status that was revealed in our comprehensive research conducted over multiple years by creating the Categorical Adjustment Index (CAI). We also note that CMS is implementing multiple model tests focused specifically on populations with social risk factors, such as the Medicare-Medicaid Financial Alignment Initiative.

Question: 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?

Response: This regulation is under review by the Administration. I share your interest in this issue and should note that access to durable medical equipment for Medicare beneficiaries is a priority for the Department.

Question: 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?

Response: We support the goal of improving the process for approval and coverage of innovative products and reducing the time between FDA marketing approval or FDA's granting of a de novo request and Medicare coverage decisions through CMS's National Coverage Determination (NCD) process. Under the FDA-CMS Parallel Review Program, the agencies concurrently review medical devices to help reduce the time between the FDA's approval of a device and Medicare coverage. This voluntary program is open to certain premarket approval applications for devices with new technologies and to medical devices that fall within the scope of a Part A or Part B Medicare-benefit category and have not been subject to a national coverage determination.

Question: 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?

Response: SAMHSA regulates Opioid Treatment Programs through an initial certification process and ongoing accreditation oversight. SAMHSA also manages the DATA 2000 waiver program for physicians, physician assistants, and nurse practitioners that provide office-based prescribing of certain FDA-approved medications for opioid use disorder. In addition to management and oversight of STR Grantees, SAMHSA is providing ongoing technical assistance (TA) to all grantees using conferences, webinars, learning collaboratives, and the Opioid State Targeted Response TA program. Evidence-based MAT prescribing, supported by a variety of SAMHSA tools and resources, is an essential aspect of this TA.

SAMHSA required states to identify the evidence-based practice that they intended to use in their initial application for STR funds and in their strategic plans submitted in August of 2017. Grant project officers have monthly calls with each state to discuss progress on implementation of their plans and any concerns that either the state or SAMHSA has with progress. Grant project officers are also making site visits to states to meet with state staff and providers and patients to understand the implementation process on the ground. States are required to report twice a year on a set of questions including the numbers of people that received specific services. Additionally, the program is being evaluated by an external evaluator. The evaluation includes an assessment of use of evidence-based practices.

SAMHSA also recently released a fact sheet, "Finding Quality Treatment for Substance Use Disorders." This fact sheet provides individuals and families with some of the right questions to ask when looking for quality treatment, including whether the treatment program is licensed or certified by the state, whether the program offers FDA approved medications, whether the program includes family members in the treatment process, and whether the program provides

other supports in addition to treatment. The fact sheet is on SAMHSA's website:
<https://store.samhsa.gov/shin/content//PEP18-TREATMENT-LOC/PEP18-TREATMENT-LOC.pdf>.

Question: 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 nonquantitative 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?

Response: HHS is working collaboratively with the Departments of Labor and the Treasury to implement the provisions of Title XIII of the 21st Century Cures Act (P.L. 114-255). On April 23, 2018, the Departments published the parity compliance program guidance document required by section 13001 (a) the 21st Century Cures Act (the Act). On that date, the Departments also issued the parity documents required by section 13001(b) of the Act, which includes guidance regarding both non-quantitative treatment limitations as well as disclosure and other guidance provided in the form of proposed FAQs about Mental Health and Substance Use Disorder Parity Implementation and the Act, and, finally, a re-proposed model disclosure form. On January 11, 2017, the Employee Benefits Security Administration (EBSA) released its annual MHPAEA Enforcement Fact Sheet summarizing the agency's closed federal MHPAEA investigations and findings in fiscal year 2016. EBSA recently released its Fiscal Year 2017 MHPAEA Enforcement Fact Sheet, which reports its closed investigations and findings of violations for Fiscal Year 2017. All of these documents can be found on the EBSA website, <https://www.dol.gov/agencies/ebsa>.

In December 2017, HHS posted a Mental Health Parity and Addiction Equity Act Enforcement Report. That report is available here: <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/HHS-2008-MHPAEA-Enforcement-Period.pdf>

Question: 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?

Response: As you know, in order to increase benchmarks in Puerto Rico as a percentage of FFS costs, a statutory change would be necessary. The policies proposed in the 2019 Advance Notice and Draft Call Letter will provide stability for the Medicare Advantage program in the Commonwealth and to Puerto Ricans enrolled in MA plans. These policies include basing the Medicare Advantage county rates on only the relatively higher costs of beneficiaries in Fee-For-Service Medicare who have both Medicare Parts A and B, interpreting the criteria used to determine which counties qualify for an increased quality bonus adjusted benchmark in a way that permits certain Puerto Rican counties to qualify, and applying an adjustment to Puerto Rico FFS costs to reflect the nationwide propensity of beneficiaries with zero claims. In addition, in recognition of the impact that recent natural disasters might have on the underlying operational and clinical systems that CMS relies on for accurate performance measurement in the Star Ratings program, CMS is proposing a variety of strategies to address Star Ratings issues related to plan contracts impacted

by extreme and uncontrollable circumstances, in Puerto Rico and elsewhere. This includes adjusting the 2019 and 2020 Star Ratings to take into account the effects of extreme and uncontrollable circumstances that occurred during the 2017 performance period, such as Hurricanes Harvey, Irma, and Maria, and the wildfires in California. We remain committed to working together with you to maintain a strong, sustainable MA and Part D program for Puerto Rico and our nation's Medicare beneficiaries.

Long: 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?

Response: As you know, the Medical Loss Ratio (MLR) provision requires issuers to spend a certain amount of revenue on medical care and quality improvement activities. We have and will continue to look to provide as much flexibility to the states and issuers as is permitted under the statute. For example, HHS recently proposed modifications to reduce the burden on issuers and states related to the MLR. I am happy to look into this issue and get back to you.

Representative Long

Question: 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.

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.

Response: HHS has multiple roles with respect to cybersecurity. With respect to our role as a Federal Department and a provider of public services we are responsible for the security of internal systems across the Department's Operating and Staff Divisions. We are also a regulator of certain aspects of healthcare industry cybersecurity, especially with respect to the privacy and security of patient information, including electronic protected health information, and the safety of medical devices and other regulated healthcare products. On the non-regulatory side, we are designated the Sector-Specific Agency (SSA) for the Healthcare and Public Health Sector under Presidential Policy Directive 21. As an SSA we are responsible in part for serving as a "day-to-day Federal interface for the dynamic prioritization and coordination of sector-specific activities" with the Healthcare and Public Health Sector.

While there are components of these responsibilities that must remain separate in order to maintain the integrity of our internal and regulatory programs, we coordinate whenever and wherever possible. The HHS Deputy Secretary (currently Eric D. Hargan) serves as the senior official responsible for coordinating cybersecurity activities across the Department. Mr. Hargan convenes the HHS Cybersecurity Working Group, which brings together representatives from all Operating and Staff Divisions with cybersecurity responsibilities for senior-level coordination on policy and program matters.

The Office of the Assistant Secretary for Preparedness and Response (ASPR) works on behalf of the Department to coordinate private sector partnership efforts related to cybersecurity and other critical infrastructure protection matters. ASPR does not do this alone, but relies on a Government Coordinating Council (GCC) of HHS, other Federal Department and Agency, and state and local government partners to provide a unified governmental voice to the private sector. This GCC interfaces with a Sector Coordinating Council (SCC) composed of major national trade associations and large, medium, and small companies from across the breadth of the Healthcare and Public Health Sector. Among the current collaborative cybersecurity efforts undertaken by this partnership are the analysis of cyber risk across the Sector, the identification of cyber-dependent critical infrastructure, the development of guidelines and best practices for enhancing cybersecurity, and the sharing of cyber threat and vulnerability information.

Subject matter experts within the Office of the Chief Information Officer are an essential component of all of these collaborative efforts with the private sector. For example, ASPR is working closely with the Healthcare Cybersecurity and Communications Integration Center (HCCIC) to address one of the most important findings of the Health Care Industry Cybersecurity Task Force, which is the imperative to “improve information sharing of industry threats, risks, and mitigations.” With its unique perspective within HHS and its relationships with the Defense Health Agency and Veterans Health Administration (including through the Healthcare Threat Operations Center), the HCCIC has access to a wide range of information on cyber threats impacting healthcare organizations. Working through the ASPR-coordinated private sector partnership and in close coordination with the Department of Homeland Security, HCCIC is able to fuse this information with information received from industry partners and develop products that are shared with the private sector through ASPR’s standard information sharing mechanisms.

Question: 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?

Response: The Healthcare Cybersecurity and Communications Integration Center (HCCIC) resides within the Office of the Chief Information Officer (OCIO), within the Office of the Assistant Secretary for Administration (ASA). While the HCCIC provides information analysis for sharing with the private sector, it also has functions that are internally focused and essential to the protection of HHS information systems. When HCCIC shares information with the private sector, it is done in close coordination with the Department of Homeland Security and within the public-private sector collaboration structures established by the Office of the Assistant Secretary for Preparedness and Response (ASPR), as the lead HHS component with respect to HHS’s obligations as the Sector Specific Agency for the Healthcare and Public Health Sector under PPD 21.

Question: 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?

Response: The Healthcare Industry Cybersecurity Task Force report has provided HHS and our industry partners with a roadmap for improving cybersecurity across our organizations. The challenge is large, and there is much work to be done. We believe that many of the efforts we are undertaking now, including expanding our information sharing systems and developing guidelines and best practices under Section 405(d) of the Cybersecurity Act of 2015, will go a long way toward improving cybersecurity across the Sector. In everything we do, we must continue to rely on and leverage the expertise of our private sector partners. We are encouraged by the dedication they are showing this issue and their current efforts to respond to the Task Force recommendations. As cybersecurity concerns continue to challenge us, we must continually seek to expand the depth and

breadth of our private sector engagements to build a more secure and resilient Healthcare and Public Health Sector.

Representative 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.

Response: We appreciate the urgency of the situation in Oklahoma. As you may be aware, the state submitted an amendment to its 1115 demonstration in order to receive supplemental payments for Oklahoma public universities that offer qualified physician residential training programs, and to offer a physician qualified loan repayment program. On February 1, 2018, CMS alerted the state that its application was complete, and posted the amendment request on Medicaid.gov for a 30-day Federal public notice and comment period, which closed on March 4th, 2018. After careful review of the state's proposal and evaluation of the demonstration amendment requests against the specific statutory authorities that establish the Medicaid program, CMS alerted the state, on April 17, 2018, that it will not approve Oklahoma's amendment request as it is currently written. Since the issuance of that letter to the state, CMS has been actively engaged with the state to find an approvable path forward.

Representative Pallone

Question: 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?

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?

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.

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

Response: Our existing partnerships with healthcare providers, clinicians, states, payers and stakeholders have generated important value and lessons and CMS is setting a new direction for the Innovation Center. That is why, in September 2017, CMS released a Request for Information (RFI) seeking public feedback on ways to promote patient-driven care and test market-driven reforms that empower beneficiaries as consumers, provide price transparency, increase choices and competition to drive quality, reduce costs, and improve outcomes. We are grateful for the comments and thoughtful ideas that we received in response to the RFI. Overall, through the close of the comment period in November, CMS received approximately 1,000 submissions. CMS continues to review these submissions, and they will be an integral source of information as CMS moves forward with the agency-wide efforts to promote innovation, including through the design and testing of additional Advanced APMs that will aim to improve the patient-provider experience. However, our engagement with stakeholders has not ended with this RFI and we look forward to continuing to working with all stakeholders to make sure we are delivering results and putting the patient in the driver's seat. We are committed to following the Administrative Procedures Act (APA) and while the comments were not solicited as part of any proposed rule, and therefore CMS is not obligated to post the comments, we plan to make comments available on the Innovation Center's website and are happy to work with you and relevant stakeholders to share any additional information as needed. We are happy to engage with you and your staff and provide additional information you may need on the work of the CMS Innovation Center.

Question: 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.

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?

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

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.

What process did HHS use to review these submitted waivers?

Response: CMS has worked over the years to enhance policy and practice to increase transparency and to ensure the public has sufficient notice and opportunity for meaningful input on state section 1115 proposals submitted for Federal consideration, while also being mindful of the need to avoid

duplicative processes and unnecessary administrative burdens and delays as we work with states to test new approaches in response to rapidly evolving state and Federal health policy.

With the enactment of the Affordable Care Act, Congress set forth additional requirements to increase the degree to which information about Medicaid and CHIP demonstration applications and approved demonstration projects is publicly available and to further enhance transparency in the Federal review and approval of section 1115 demonstration applications. Specifically, the Affordable Care Act amended section 1115 of the Act by adding a new subsection (d) to require the Secretary to issue regulations that would ensure the public has sufficient opportunities to provide meaningful input into the development of state demonstration projects, as well as in the Federal review and approval of state demonstration applications and renewals. This required the establishment of a process to provide for public notice and comment at the state level before a demonstration application is submitted to the Secretary and then again at the Federal level once a complete application is submitted but has not yet received a final HHS determination.

Effective April 27, 2012, CMS published a final rule which established a formal process for seeking public input and increases the degree to which information about Medicaid and CHIP demonstration applications is publicly available. The regulation also establishes a process so that the development and review of demonstration applications proceeds in a timely and responsive manner. Pursuant to the final rule, states must provide at least a 30-day public notice and comment period for applications for new demonstrations and extensions of existing demonstrations. Once a State's 30-day public comment period has ended, the State will submit an application to CMS. Within 15 days of receipt of the application, CMS will determine whether the application is complete. CMS will send the State written notice informing the State of receipt of the complete application, the date on which the Secretary received the application, and the start date of the 30-day Federal public notice period. If CMS determines that the application is not complete, CMS will notify the State of any missing elements in the application.

HHS and CMS take these transparency requirements seriously as we believe that public engagement and input is vital to successful state demonstrations approved under section 1115 authority. In addition to the requirements outlined in the ACA and the final rule, HHS and CMS continues to engage with states and stakeholders throughout the entire demonstration approval process to ensure a successful and workable demonstration. CMS evaluated and approved each of the waivers mentioned above under these requirements, and we will continue to adhere to these requirements as we consider pending 1115 waiver applications and renewals.

Question: 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 "statebased 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".

Response to 1-4: I am committed to working with states to grant flexibility wherever appropriate to provide their citizens the best possible access to healthcare. However, the Affordable Care Act remains the law. CMS informed the State that its State-based plan proposal, as originally issued, is inconsistent with the law.

The Department looks forward to working to explore ways in which Idaho can achieve its policy goals while ensuring that health insurance coverage sold within the state complies with all applicable federal laws and requirements.

Question: 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?

Response to 1-2: Please note that the previous Administration proposed that the open enrollment period be shortened to the current length starting for the 2019 plan year, and that this policy aligns more closely with the one month open enrollment periods we typically see in the employer-sponsored insurance market and the seven week Medicare open enrollment period, the two markets where the vast majority of Americans are successfully enrolled, year after year.

I will examine the data and work with the Administrator to make the best, evidence-based decisions, balancing prudent use of resources with faithful execution of the law. As it relates to advertising expenditures, it is my understanding that the current level of spending is consistent with what is spent on promotion for Medicare Advantage and Part D, and that Navigators were funded at levels based partly on their ability to meet their enrollment goals from the prior year, so as to inject accountability into that program.

Ultimately, Congress will need to act to make the broader reforms that are needed in order to create a health insurance system that is more affordable and responsive to the needs of individuals and their families. I have been encouraged by the efforts ongoing in Congress to address the issues, and look forward to continuing to work with you to support these efforts.

Question: 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?

Response: Short-term, limited-duration insurance plans are flexible, adaptable insurance products that can be particularly useful for those entering the job market, those transitioning between jobs and other forms of insurance, or who are otherwise priced out of the unaffordable ACA insurance markets. Americans need more insurance options, and they need less Federal micromanagement of their insurance options.

The status quo is not working for millions of Americans – whether it is those who are in the insurance market or those who have been left out of it. Although there are many Americans who may not be best served by a short-term, limited-duration plan, expanding the availability of such plans creates affordable options for those who understand how to choose and use these flexible, short-term products. HHS is working with the Departments of Labor and the Treasury, and across the Executive Branch, to create a health insurance system that is more affordable and responsive to the needs of individuals and their families, so that we have a healthcare system that is more affordable and accessible, where individuals and their families can choose the type of insurance coverage that works best for them, including the option of short-term, limited-duration insurance. The changes to short-term, limited-duration plans in the proposed rule are intended to provide additional, often much more affordable coverage options. The comment period on the proposed rule ended on April 23, 2018. I will work to ensure the least disruptive approach to implementing these policies, and to appropriately consider the concerns expressed by stakeholders during the rulemaking process.

Question: 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.

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?

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?

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?

Response: Drug prices are too high. The President has made this clear and, as you note, the President’s FY 2019 Budget includes a number of legislative proposals to reduce the prices Americans pay for prescription drugs. Additionally, I would be happy to work with you and others in Congress on legislative changes such as the FAST Generics Act and the CREATES Act. I also support the FDA’s ongoing efforts to review its regulatory authorities to identify those abuses which can be addressed under existing authorities, those which require a coordinated, cross-government action, and those which require legislative changes. I am particularly concerned about the issues of (1) branded companies using REMS programs to prevent the study of the drug and approval of a generic form of the reference drug subject to REMS, (2) branded companies limiting supplies of reference product on which to conduct needed studies, and (3) branded companies securing patented modifications to the underlying product and withdrawing the previously approved product from the market, thus making entry of a generic competitor to that earlier version of the product more time consuming and difficult. In addition, the Food and Drug Administration Reauthorization Act of 2017 (FDARA), which was signed in to law last year, clarified that FDA may require a drug be superior to other drugs on the market in order to receive market exclusivity. I expect Dr. Gottlieb and FDA will implement these clarifications and look forward to reviewing whether incentives for innovation are adequately balanced with timely access to generic competition as intended under the Hatch-Waxman Act.

Question: 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.

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

Response: Our Medicaid program is an important tool in providing healthcare to many Americans but we must put it on a stable long-term sustainable footing for it to be there for this and future generations. That is the challenge that we have as we seek to empower the states with the right incentives to deliver quality service. The FY 2019 Budget provides additional flexibilities to states, puts Medicaid on a path to fiscal stability by restructuring Medicaid financing, and refocuses on the populations Medicaid was intended to serve—the elderly, people with disabilities, children, and pregnant women. Annual Federal Medicaid spending will grow from \$421 billion in FY19 to \$702 billion in FY28 over the budget window. The FY 2019 Budget also repeals the Medicaid expansion and the Exchange program subsidies and replaces these programs with the \$1.2 trillion Market-Based Health Care Grant program through the Graham-Cassidy-Heller-Johnson legislation.

Opioid misuse, abuse, and overdose impose immense costs on the Nation, contributing to two-thirds of deaths by drug overdose. Deaths by drug overdose are the leading cause of injury death in the United States. The FY 2019 President’s Budget recognizes the devastation caused by the opioid crisis in communities across America and fulfills the President’s promise to mobilize resources across the Federal Government to address the epidemic. The Budget provides a historic level of new resources across HHS to combat the opioid epidemic and serious mental illness—\$10 billion—to build upon the work started under the 21st Century Cures Act.

The Budget’s targeted investments advance the Department’s five part strategy, which involves:

- **Improving access to prevention, treatment, and recovery services, including medication-assisted treatment;**
- **Targeting availability and distribution of overdose-reversing drugs;**
- **Strengthening our understanding of the epidemic through better public health data and reporting;**
- **Supporting cutting edge research on pain and addiction; and**
- **Advancing better practices for pain management.**

Question: 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.

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.

Response: The Budget makes a substantial investment in addressing the opioid crisis. It targets the funding to help HHS address all five points of our strategy, including improving access to treatment and recovery services. The Budget proposes \$1 billion for the State Targeted Response to the Opioid Crisis program. This will allow states to develop their own targeted approaches to prevention, treatment, and recovery support. In addition, health centers will receive \$400 million to help address substance abuse, including opioid abuse, and the overdose crisis. The Indian Health Service would receive \$150 million to provide multi-year grants based on need for opioid abuse prevention, treatment, and recovery support. We also propose to require Medicaid to cover all medication-assisted treatment and Medicare to conduct a demonstration to test the effectiveness of covering comprehensive substance abuse treatment in Medicare.

Question: 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:

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.

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.

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

Response: "First filer" generic drugs that are approvable from a patent/exclusivity perspective, but unapprovable due to substantive deficiencies, can block subsequent applicants under the current 180-day exclusivity provisions of the Federal Food, Drug, and Cosmetic Act for extensive periods of time. Frequently, the substantive deficiencies occur in the inspection of the first filer's manufacturing facilities. Similarly, first filer ANDAs that receive tentative approval but then intentionally delay seeking final approval can block subsequent ANDA approvals. As a result, first filers can "park" their exclusivity and block subsequent generic competitors, and consumers are denied access to generic products and must keep paying brand price. We estimate that first filer ANDAs block the approval of subsequent ANDAs solely as a result of 180-day exclusivity approximately 5 times a year on average.

As you note, the President's Fiscal Year 2019 Budget includes an important legislative proposal to help address this issue. The proposal generally makes the eligibility for tentative approval of a subsequent generic drug applicant that is blocked solely by a first filer's 180-day exclusivity, where the first filer has not yet received final approval, a trigger of the first filer's 180-day exclusivity. Thus, this new trigger would not apply in situations in which the approval of the subsequent applicant was blocked by a 30-month stay or by another patent or exclusivity other than a first filer's eligibility for 180-day exclusivity.

The proposal would not undermine the value of 180-day exclusivity, but would instead address a gap in the current 180-day exclusivity provisions that allows first filers to block generic competition in some situations, either because their application has significant deficiencies that they have not corrected, or because the first filer is deliberately parking its exclusivity by failing to seek final approval once any deficiencies in its application are remedied. The proposal would incentivize first filers to submit quality applications and to seek timely approval of their applications once patent and exclusivity issues with respect to the innovator have been resolved, rather than engaging in gaming tactics that can block subsequent applicants and deny consumers the benefit of generic competition.

Thus, this proposal will enhance competition, facilitate more timely access to generic drugs, and is expected to create meaningful savings.

Question: 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.

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

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?

Response: On April 16, 2016, CMS issued a State Medicaid Director (SMD) letter that provided guidance to state Medicaid agencies on compliance with section 1902(a)(23) of the Social Security Act (the Act), which is often referred to as the “free choice of provider” provision. CMS rescinded this letter on January 19, 2018, due to concerns that the 2016 Letter raises legal issues under the Administrative Procedure Act, as well as limiting state flexibility with regard to establishing reasonable Medicaid provider qualification standards. States are still subject to the requirements under Sec. 1902(a)(23) and 42 CFR sec. 431.51 regarding free choice of providers.

Question: 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.

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?

Response: The Department is committed to the statutory language governing the Title X program. Accordingly, the most recent Title X family planning services FOA requires Title X projects to offer a broad range of voluntary family planning methods and services, including information and education related to family planning, preconception care, contraception, natural family planning, and infertility services. Such methods and services range along a continuum of care, tailored to the unique needs of the individual. This includes all required services as stipulated in 42 CFR § 59.5, which ensure breadth and variety among family planning methods offered. Specific services mentioned in the FOA within the section on Program Priorities also include cervical and breast cancer screening, prevention of STDs, and HIV prevention education, counseling, testing and referrals.

Question: 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.

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

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.

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.

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?

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

Response: Over the past five years, the Office of the Assistant Secretary for Health (OASH) has worked with the Office of Population Affairs (OPA) to streamline administration of the Title X family planning program, so that it would be administered like all other OASH grant programs. The FY 2018 Title X family planning services FOA is the culmination of that effort. This effort includes realigning Title X service areas, award start dates, and competitive reviews to more efficiently administer the program. This year's Title X grants also included a number of reforms to simplify the process for applicants, such as allowing organizations that work across multiple states to submit just one application, rather than multiple applications.

The Department is committed to the statutory language governing the Title X program. Accordingly, the most recent Title X family planning services FOA requires Title X projects to offer a broad range of voluntary family planning methods and services, including information and education related to family planning, preconception care, contraception, natural family planning, and infertility services. Such methods and services range along a continuum of care, tailored to the unique needs of the individual. This includes all required services as stipulated in 42 CFR § 59.5, which ensure breadth and variety among family planning methods offered. Specific services mentioned in the FOA within the section on Program Priorities also include cervical and breast cancer screening, prevention of STDs, and HIV prevention education, counseling, testing and referrals.

The Department and OPA strongly support Title X clients receiving quality family planning methods and services. As such, the latest Title X family planning services FOA contains references to CDC's guidelines on sexual health assessments and reproductive life plans. The QFP Guidelines were released in 2014.

Title X family planning service sites are not required also to provide primary healthcare services, other than those related to providing family planning services (for example, cervical cancer and STD screening). While comprehensive primary care providers are eligible and encouraged to apply for a Title X grant under the most recent Title X family planning services FOA, primary care services that are not related to providing family planning cannot be provided as part of Title X grant activities. Nevertheless, it is best for patients to have primary care services provided within the same site or for the family planning provider to have robust referral linkages to primary care providers within close proximity to the Title X site. Either of these options helps promote optimal physical, emotional, and social health outcomes, which is the ultimate goal of client-centered care.

While the Department cannot comment on regulatory plans, the Administration's Unified Agenda of Regulatory and Deregulatory Actions, as provided through the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA), includes "Compliance With Title X Requirements By Project Recipients in Selecting Sub recipients," an action that would withdraw the amendment made in a December 2016 Final Rule in conformity with the enacted joint resolution of disapproval under the Congressional Review Act.

Question: 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?

Response: With regard to the recent news about CDC reducing its global presence, CDC is in the process of planning, as the \$1.2 billion supplemental Ebola/Global Health Security funding awarded to CDC in FY 2015 expires at the end of FY 2019. However, the U.S. commitment to global health security and the Global Health Security Agenda (GHSa) specifically, remains steadfast.

The President's FY 2019 President's Budget includes \$59 million for CDC to continue activities that support Global Health Security Agenda implementation—evidence of the continued commitment. The \$59 million for GHSa in the President's FY 2019 Budget are bridging funds that would be used to support the continued development of core public health capabilities in GHSa priority countries as CDC transitions from the funding surge provided by the emergency supplemental funding to the next phase of GHSa implementation.

The U.S. Government strongly supports the GHSa and its objectives to build capacity to prevent, detect, and respond to infectious disease threats at their source. As President Trump has publicly stated, and as reaffirmed by U.S. Administration officials at the GHSa Ministerial Meeting in Uganda in October 2017, the U.S. Government strongly supports the extension of GHSa through 2024.

Many agencies contribute to the U.S. Government's commitment to GHSa, including the U.S. Department of State, Department of Health and Human Services, Department of Defense, U.S. Department of Agriculture, U.S. Agency for International Development, and CDC, through base and supplemental funding. CDC remains committed to the U.S. Government's investment in GHSa partner countries and continuing long-standing work to build health security capacities.

Question: 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."

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?

Response: In this constrained budget environment, difficult decisions had to be made across the Federal Government, including at the Centers for Disease Control and Prevention (CDC). The President's Budget attempted to prioritize public health risk.

The Administration submitted an addendum to the FY 2019 Budget that includes additional funding for a limited set of Administration priorities under the new, higher cap levels. Additional funds for CDC in the addendum include an additional \$100 million for chronic disease prevention programs.

CDC will continue to conduct critical science and provide health information that protects our nation against expensive and dangerous health threats, and responds when these arise.

Question: 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.

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?

Response: Within CDC, the WTC Health Program will continue to provide medical monitoring and treatment for responders at the WTC and related sites in New York City; in Shanksville, Pennsylvania; and at the Pentagon; and to survivors who were in the New York City disaster area with the goal of no service disruption. The WTC Health Program aligns with CDC's mission to protect America from health, safety, and security threats, both foreign and in the United States. HHS looks forward to engaging with individuals from the 9/11 health community.

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?

Response: The WTC Health Program would continue to execute its statutory responsibilities through a WTC Program Administrator as defined by Section 3306 of the PHS Act.

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?

Response: Within CDC, the WTC Health Program will continue to provide medical monitoring and treatment for responders at the WTC and related sites in New York City; in Shanksville, Pennsylvania; and at the Pentagon; and to survivors who were in the New York City disaster area with the goal of no service disruption. The WTC Health Program aligns with CDC's mission to protect America from health, safety, and security threats, both foreign and in the United States.

Question: 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.

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?

Response: Several Congressional inquiries have reviewed this matter. If you are interested in viewing our responses, we will provide them.

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

Response: The Inspector General announced in September that they are reviewing this matter as requested by your office. Out of respect for their process we are awaiting the completion of their review.

Question: 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?

Response: During my tenure I will always strive to be a responsible steward of taxpayer dollars. I expect the same of Department employees.

Question: 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. 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?

Response: Pursuant to Departmental policy, prior to entering Government service at HHS, the Ethics Division reviews the reported financial interests of each potential political appointee, including those imputed to the individual; determines whether any of the interests create a conflict or appearance of a conflict under the rules; and document in an Ethics Agreement a method for resolving these conflicts. Under the Ethics in Government Act, conflicts are resolved through recusals, divestiture, waivers, authorizations, reassignment, and other appropriate means.

Question: 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? 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?

Response: All political appointees, like all Members of Congress, are required to file a public financial disclosure statement that includes reports all of the individual's financial interests. The Stop Trading on Congressional Knowledge (STOCK) Act requires all public financial disclosure filers to file timely updates of any financial transactions that exceed \$1,000. Individuals who fail to meet their filing requirements in a timely matter are subject to \$200 late fees. Individuals who fail to file or who falsify reports can be subject to criminal action, civil penalties up to \$59,028, and other appropriate personnel action.

Representative Eshoo

Question: 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?

Response to 1-5: I look forward to working across the Administration and with Congress to ensure that women have access to the care they need – that may include care for cancer, diabetes, maternity care, family planning, cardiovascular health and many other issues affecting women, men and families – while simultaneously implementing the many conscience-protecting statutes that Congress has enacted in healthcare. We are working to provide more options for individuals and families by making healthcare and healthcare insurance more affordable, so that Americans have access to the care that they need.

Question: 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.

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?

Have you met with a Medicaid recipient?

Response: Stakeholder feedback is a vital part of CMS’s work across all of our programs, including Medicaid. In addition to following HHS’s standard rulemaking process, which involves seeking feedback from the public, HHS uses several other methods to gather input from patients, providers, plans, and state and local officials when designing improvements to our programs. For example, I recently traveled to Ohio to participate in a listening session at an inpatient care facility, where I was able to hear from local officials, providers, families, and children about how opioid addiction has impacted them.

Medicaid is a safety net program that provides coverage for life-saving medical care to millions of Americans facing some of the most challenging health circumstances. In addressing the diversity and complexity of Medicaid recipients, we have a duty to ensure the highest level of quality, accessibility, and choices for Americans who rely on the program, including those who need mental health services and substance abuse treatment. For that reason, it is crucial for states to have the flexibility to tailor the Medicaid program to meet the needs of their constituents. I am working to ensure that states are empowered to tailor solutions that work for their citizens with mental illnesses and substance use disorders and that they receive the proper supports from their federal partners at HHS. Our aim is to restore a strong state-federal relationship while also modernizing

the program to deliver better outcomes for all populations being served. We need a system that will provide stability and predictability for both state and Federal budgets, and most importantly, will protect future recipients by ensuring the Medicaid program's long-term viability.

Question: 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?

Response: Project BioShield (PBS) was initially supported under the Special Reserve Fund (SRF), an advanced appropriation of \$5.6 billion (2004). The SRF was meant as a market guarantee to encourage participation from industry in the development of critical medical countermeasures (MCMs) to address chemical, biological, and radiological and nuclear (CBRN) threats. For the vast majority of these critical MCMs, there is no other market outside the U.S. government. Contracts that were awarded under the SRF supported all late-stage activities and an initial procurement of product. The options that were included were for additional procurement to increase preparedness or replenish expiring product. This type of contract, full support and procurement in the base award, fulfilled the market guarantee intended under PBS. PBS was reauthorized in 2013 under the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), which authorized appropriations of \$2.8 billion for FYs 2014 – 2018. Starting in FY 2014, yearly appropriations have been provided to support PBS activities. Even though additional progress continues to be made by supporting new products under PBS, our private sector partners no longer have the long-term market guarantee that an advance appropriation provides. PBS funding has been provided at \$255 million for FY 2014, \$255 million for FY 2015, \$510 million for FY 2016, \$510 million for FY 2017, and anticipated \$710 million for FY 2018. This equates to \$2.240 billion of the \$2.8 billion authorized.

Question: Starting in FY 2014, fourteen new products have been supported under PBS. The success in transition of products from advanced research and development (ARD) to PBS is because of the funds provided for ARD starting in FY 2007 under the 2006 Pandemic and All-Hazards Preparedness Act (PAHPA). The success has led to more products becoming eligible for transition to PBS, but with insufficient yearly PBS funding to support all late-stage activities and initial procurements in the base award(s), as was done under the SRF. As a result, PBS contract awards starting in FY 2014 only included support for a portion of the necessary late-stage development activities in the base award. The remaining late-stage activities are included as options that could only be executed based on availability of funds. The procurement of product is also included as an option(s). Therefore this model no longer supports the market guarantee intended under PBS. Additionally, this has had a domino effect on funding availability, since new PBS products funded in FY 2014 or 2015 have additional out year costs that further decrease the level of downstream available funding for new starts in later fiscal years, even when funding increased to \$510 million per year.

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

Response: Please refer to the response to the question above. In addition, advanced appropriations will restore PBS funding, providing the intended market guarantee that was established under the SRF. It will allow for full funding of all late-stage activities and procurement of product in the base award. The options will provide additional procurements to increase preparedness or replenish expiring product.

Question: 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?

Response: Much of this funding has traditionally supported state health departments to prepare for and respond to outbreaks of infectious disease and antibiotic resistance. In this constrained budget environment, difficult decisions had to be made across the federal government, including at CDC. CDC's NCEZID will continue to conduct critical science and provide health information that protects our nation against dangerous health threats.

Representative DeGette

Question: 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?

Response: All Medicare DMEPOS suppliers must furnish items that are cleared by the FDA as safe and effective and all suppliers must be in compliance with the Medicare supplier standards and quality standards. If a Medicare DMEPOS supplier furnishes items that do not comply with FDA standards or Medicare standards and requirements; they will be dealt with through use of our existing authorities and remedies.

Representative 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?

Response (1 and 2): The Department has replied to an inquiry from Ranking Member Cummings on this issue, and a copy of our response will be provided to your office. Department issued guidance documents, regulations, or written proposals will always be a product of the Department's own deliberative process. I think it is important to note, however, that policy proposals from outside interest groups are commonplace, and a means by which citizens exercise their First Amendment right to petition their government.

Representative Butterfield

Question: 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?

Response: Yes, I agree FDA plays a critical role in evaluating potential benefits and potential risks and assuring patient safety. FDA takes seriously its core mission to help ensure the safety and efficacy of the medicines upon which patients depend. Adequate policies and processes must be in place to appropriately balance individual patients' needs for access to investigational therapies while recognizing the importance of maintaining a rigorous clinical trial paradigm for testing investigational products to demonstrate safety and efficacy.

FDA's expanded access program is operating efficiently, demonstrated by the fact that currently, 99.6 percent of individual requests are allowed to proceed, and usually within a very short time period.

Question: 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?

Response: See answer above.

Representative Matsui

Question: 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.

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

Response: I understand that enhancing the efficient, effective, consistent, and transparent regulation of combination products is a top priority for FDA. The Office of Combination Products (OCP) was established on December 24, 2002, as required by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). The 21st Century Cures Act made further revisions to facilitate the timely review of, and feedback on, applications for combination products. OCP is taking a variety of actions to support the development and regulation of combination products, including: developing policies to clarify and streamline premarket and post market expectations; implementing more efficient inter-center consultation processes; enhancing staff training; updating IT systems; and pursuing ongoing assessment of policies, systems, and procedures.

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

Response: Yes. Section 3038 of the 21st Century Cures Act provides mechanisms to streamline and enhance the clarity and certainty of the combination product review process, which will enhance the potential for combination product competition. FDA efforts discussed above in response to question-1 intend to facilitate efficient, consistent, and predictable combination product regulation, including streamlining the review process of all premarket applications and reporting requirements of post market adverse events.

By improving the inter-center consult process and clearly conveying FDA's regulatory and scientific expectations to stakeholders, the Agency will be able to meet its commitment of ensuring timely and effective review of combination products. The sooner generic versions of combination products are approved, the more choices can be available to patients, enhancing the potential for competition.

Question: 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.

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?

Response: I can assure you that FDA supports the goal of using science-based methods to incorporate patients' voices into drug development and the regulatory decision-making process. Both the Cures Act and PDUFA VI included enhancements to facilitate the patient voice in the regulatory decision process.

FDA has begun implementing the patient-focused drug development provisions in the Cures Act. This includes, for all new drug applications approved at least 180 days after the Cures Act enactment, the requirement to make public a brief statement regarding patient experience data and related information that may have been submitted and was reviewed as part of an application. This

also includes FDA's May 2017 publication of a five-year plan for the issuance of draft and final patient-focused drug development guidances to implement provisions under the Cures Act, section 3002.

On December 18, 2017, FDA held a workshop on Patient-Focused Drug Development, which allowed it to obtain feedback on standardized terminologies, methods for collection of patient data, and reporting, management, and analysis of patient input. FDA had over 600 people registered for in-person and on-line attendance. This was done as part of the work to gather public input related to the guidance content required under the Cures Act section 3002(c)(1). The agency plans to issue draft guidance related to this provision before the end of FY 2018.

In addition, FDA will hold a public workshop on March 19, 2018, to seek public stakeholder input for inform agency development of the guidance content under the Cures Act, section 3002(c)(5). This guidance relates to developing and submitting draft guidance relating to patient experience data for FDA consideration. The agency plans to issue draft guidance related to this provision before the end of FY 2018.

FDA also established a Patient Engagement Staff (PAS) within the Office of Medical Products and Tobacco (OMPT). The purpose of PAS is to:

- Serve as a single, central entry point to the Agency for the patient community.
- Provide triage and navigation services for inquiries from patient stakeholders.
- Provide a more transparent, accessible, and robust experience for patient communities.
- Host and maintain data management systems that incorporate and formalize knowledge shared with FDA by patient stakeholders.
- Provide cross-center coordination for the policies that we adopt with respect to how patients are being incorporated into the process.

The goal is to maintain and enhance FDA's existing relationships with stakeholders, and enable new groups and groups that might not already have those kinds of relationships to interact with the Agency.

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

Response: Use of Real world evidence (RWE) has the potential to make the medical product development process more efficient and less costly. RWE may also help answer questions about treatment effects and outcomes that are more generalizable to a broader patient population than those seen in a specialized research environment.

As required by the Cures Act, FDA is currently focused on developing a framework for a program that will evaluate the use of RWE to help support regulatory decisions for new indications for drugs approved under section 505(c) of the FD&C Act, or to help support or satisfy post-approval study requirements for drugs. FDA is on schedule to issue this framework by December 2018 and implement the program by December 2019. By December 2021, FDA will issue draft guidance addressing the use of RWE to help support a new indication of a drug approved under section 505(c) or to help support or satisfy post-approval requirements, including RWE data quality and standards, and analysis methodologies.

FDA is already working with stakeholders to inform these policies. FDA supported a public workshop convened by Duke-Margolis Center for Health Policy on September 13, 2017, that

discussed potential elements of a framework. FDA also supported the National Academies of Sciences, Engineering, and Medicine meetings on RWE. The first meeting was held in September 2017: Examining the Impact of Real-World Evidence on Medical Product Development: A Workshop Series | Workshop 1: Incentives, and the second meeting was held on March 6-7, 2018: Workshop 2: Practical Approaches. An additional meeting is planned for the summer of 2018 on operationalizing the collection and use of RWE.

Question: Finally, FDA has funded several demonstration projects to better understand different aspects of RWE. This includes the first randomized, controlled clinical trial conducted using the infrastructure created by the FDA's Sentinel Initiative -Implementation of a Randomized Controlled Trial to Improve Treatment with Oral Anticoagulants in Patients with Atrial Fibrillation (IMPACT-AFib) (NCT02082548) FDA has primarily used the Sentinel system to generate RWE about medical product safety.

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

Response: The NIH's All of Us Research Program, part of the Precision Medicine Initiative, will be a broad, powerful resource for researchers working on a variety of important health questions. By combining health-related information from one million or more diverse participants, much of it collected directly from the participants, All of Us will have the right scale and inclusive scope to enable research for a wide range of diseases, both common and rare. This participant-provided information matched with clinical data collected longitudinally and genomic data will help researchers understand the etiology of many types of diseases, including rare diseases that might share common pathways with other rare and common conditions.

Question: 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.

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

Response: The Administration would have serious concerns about a policy that would allow manufacturers, whose products have been approved for use by the EMA, but denied or not yet reviewed by FDA, to request a peer review of that data by a panel appointed by the FDA and paid for by the drug manufacturer. The 21st Century Cures Act did not include such language for devices.

With respect to approval of drugs, one of the critical functions of FDA reviewers is to examine and analyze the data provided by the company to ensure that the manufacturing and testing of the product meet our scientific standards and that the benefits of the product outweigh its risks. For companies seeking marketing approval of drugs, it is in their best interest to present the product's benefits and risks in the best possible light. In numerous cases, FDA reviewers raise important concerns with respect to the information submitted by the company, sometimes resulting in non-approval of the product.

The U.S. is the only country that reviews the raw clinical trial data provided by the companies seeking approval. Other countries, including every country currently included in section 802(b)(1) of the Federal Food, Drug, and Cosmetic Act, base their approval decisions on the analyses and summaries of the data provided by the companies. Unlike FDA, regulators in these countries do

not have access to the complete data sets, do not have the resources to examine the data in detail, and generally do not produce their own independent analyses.

Thus, the Administration would be concerned about any legislation if it would allow approval of drugs based on limited information, largely as interpreted in the eyes of the manufacturer, with mostly an over-reading by regulators in other countries and peer-reviewed by an outside panel, even if such panel were appointed by FDA.

Question: 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.

Question: 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.

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

Response: The Environmental Influences on Child Health Outcomes, or ECHO, Program meets the priorities of 21st Century Cures Act by incorporating historically underrepresented populations – including minorities, women, and children –in both the cohort and clinical trials components of the program. ECHO is a nationwide research program comprising 62 grant awards, 110 principal investigators, and 250 performance sites across 44 states, the District of Columbia, and Puerto Rico.

The clinical trials component of ECHO, the IDeA States Pediatric Clinical Trials Network (ISPCTN) awards provide medically underserved and rural children and their families with access to state-of-the-art clinical trials, apply findings from relevant pediatric cohort studies to children in IDeA state locations, and build pediatric research capacity at a national level. The participants in these trials incorporate a diverse set of minorities, women, and children in states with high burdens of childhood health conditions.

Also, across the NIH, for nearly 20 years, it has been the official agency policy that children must be included in all NIH-supported research involving human subjects, unless there are scientific or

ethical reasons not to include them. The NIH is committed to the inclusion of all relevant age groups, including children and older adults, in the clinical research studies and clinical trials it supports. NIH has taken several steps to implement provisions in the 21st Century Cures Act requiring NIH to publish data on relevant age categories, including pediatric subgroups. In December 2017, NIH revised its policy on inclusion, effective for applications received on or after January 25, 2019. Now titled the [NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects](#), the revised policy applies to individuals of all ages and requires NIH-supported clinical research studies to submit de-identified individual-level data on participant sex/gender, race, ethnicity, and age at enrollment in progress reports. NIH looks forward to the availability of additional data on the age of participants in clinical research studies, including more information on children.

Representative Welch

Question: 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?

Response: I 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?

Response: I support the goal of preventing the delay of generic drug development by ensuring both that interested developers have access to the reference listed drugs they need to support competing applications, and that the stalling or blocking of single shared system risk evaluation mitigation strategies (REMS) development not be used to prevent or delay the market entry of competing products.

This past November, FDA announced a two-pronged approach to address REMS issues—work to find ways to encourage use of shared system REMS and explore new steps to reduce the likelihood that branded companies can use REMS to slow generic competition. Also in November, FDA released draft guidance for industry to make it easier for manufacturers to make certain submissions as part of a shared system REMS. On November 8, 2017, FDA and FTC conducted a workshop to examine competition and high drug cost issues.

We are happy to continue working with the sponsors of legislation in this area to provide feedback on their proposed solutions.

Representative Schrader

Question: 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?

Response: Protecting children from the harms of tobacco use is indeed a high priority. Because almost 90 percent of adult smokers started smoking before the age of 18 and nearly 2,500 youth in the United States smoke their first cigarette every day, lowering nicotine levels could decrease the likelihood that future generations become addicted to cigarettes and allow more currently addicted smokers to quit more easily.

The Federal Food, Drug, and Cosmetic (FD&C) Act provides FDA with the authority to establish tobacco product standards. This includes the authority to adopt a tobacco product standard if the Agency finds that it is appropriate for the protection of the public health. In making such a finding, the Agency must consider scientific evidence concerning: (1) The risks and benefits of the proposed standard to the population as a whole, including users and nonusers of tobacco products; (2) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (3) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

To begin the process, FDA has initiated a public dialogue about lowering nicotine levels in combustible cigarettes to minimally or non-addictive levels. FDA has issued an advanced notice of proposed rulemaking (ANPRM) to obtain information regarding the issues FDA would need to address in a tobacco product standard regulation to regulate nicotine levels in combustible cigarettes and render them minimally or non-addictive. Reviewing the science and hearing from stakeholders will help FDA form the basis for regulatory action.

If FDA determines that a rule establishing a maximum nicotine level is appropriate for the protection of the public health, the next step would be for FDA to issue a proposed rule and obtain

public comment. Then, after consideration of comments from stakeholders, FDA could publish a final rule establishing a maximum nicotine level in cigarettes.

This effort is a high priority for FDA. I share Dr. Gottlieb's commitment to public health, and to moving this forward as quickly as the science and the regulatory process allow.

Representative Kennedy

Question: 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?

Response: We expect to announce members of the Pain Management Best Practices Inter-Agency Task Force in mid to late spring and a meeting will follow shortly thereafter. We look forward to convening this Task Force.

Question: 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?

Response: HHS is working collaboratively with the Departments of Labor and the Treasury to implement the provisions of Title XIII of the 21st Century Cures Act (P.L. 114-255). Federal or State law requires group health plans and health insurance issuers to disclose certain documents to participants and beneficiaries, contracting providers, or authorized representatives to ensure compliance with MHPAEA.

On April 23, 2018, the Departments published the parity compliance program guidance document required by section 13001 (a) the 21st Century Cures Act (the Act). On that date, the Departments also issued the parity documents required by section 13001(b) of the Act, which includes guidance regarding both non-quantitative treatment limitations as well as disclosure and other guidance provided in the form of proposed FAQs about Mental Health and Substance Use Disorder Parity Implementation and the Act, and, finally, a re-proposed model disclosure form. On January 11, 2017, the Employee Benefits Security Administration (EBSA) released its annual MHPAEA Enforcement Fact Sheet summarizing the agency's closed federal MHPAEA investigations and findings in fiscal year 2016. EBSA recently released its Fiscal Year 2017 MHPAEA Enforcement Fact Sheet, which reports its closed investigations and findings of violations for Fiscal Year 2017. All of these documents can be found on the EBSA website, <https://www.dol.gov/agencies/ebsa>.

In addition, as you know, in July 2017, the Departments, together with other Federal and State partners held a meeting to develop an Action Plan for improved federal and state coordination of enforcement of the Mental Health Parity and Addiction Equity Act (MHPAEA). As part of that

process, the Departments also accepted written comments from stakeholders. HHS is working diligently with the other Departments to review comments and feedback and finalize the Action Plan. More information about this process can be found here: <https://www.hhs.gov/programs/topic-sites/mental-health-parity/achieving-parity/cures-act-parity-listening-session/index.html>. We expect that the additional guidance on nonquantitative treatment limitations and the compliance program guidance document to be released this spring.

Finally, in December 2017, HHS posted a Mental Health Parity and Addiction Equity Act Enforcement Report. That report is available here: <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/HHS-2008-MHPAEA-Enforcement-Period.pdf>

Question: 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 of 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.

Response: The HHS OIG has a general practice of neither confirming nor denying the existence of any investigation it may be conducting. Therefore, despite references in public filings and elsewhere to HHS OIG involvement in a specific inquiry, HHS OIG cannot speak to ongoing matters, should there be any, at this time.

Question: 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?

Response: Disabilities that arise from neuro/mental/substance use disorders are the result of disruptions in the underlying circuitry of the brain. However, progress in developing new treatments has been slowed by the difficulty in clearly defining the structure of brain circuits and recording the complex information flow through those cells. The BRAIN Initiative® seeks to accelerate the development and application of innovative neurotechnologies by revealing how brain cells and circuits dynamically interact in time and space, and will ultimately enable new diagnostic and treatment strategies for many types of brain disorders. The BRAIN Initiative currently funds grants in 30 U.S. states.

Since 2014, the BRAIN Initiative has invested more than \$559 million in over 500 investigators across 368 awards, resulting in over 330 publications. Of these awards, 84 have involved human subjects research, and 16 have targeted therapeutic interventions for nine distinct disorders.

Going forward, the tools and technologies developed through the Initiative will continue to enable a deeper understanding of how the brain functions normally and what goes wrong in neuro/mental/substance use disorders. BRAIN Initiative investigators are developing imaging techniques to generate accurate ultra-high resolution brain images that reflect brain activity as opposed to simply brain structure. Other researchers are working to visualize fine structures within the brain and to map brain activity with unprecedented spatial and temporal resolution.