

November 28, 2017

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Dear Mr. Azar,

On November 14, 2017, President Donald Trump nominated you to serve as the Secretary of the Department of Health and Human Services (“HHS Secretary”).¹ On November 29, 2017, you will appear for a confirmation hearing before the U.S. Senate Committee on Health, Education, Labor, and Pensions (“HELP Committee”).²

If confirmed, you will take charge of the Department of Health and Human Services (“HHS”) in the wake of former Secretary Tom Price’s resignation.³ In February 2017, Mr. Price was sworn in as HHS Secretary after a rushed confirmation process left key questions about his suitability for the job unanswered.⁴ After a set of confirmation hearings that highlighted Mr. Price’s potential violations of ethics laws—in particular, his decision to actively trade in pharmaceutical, healthcare, and biomedical company stocks while writing policy that could affect the healthcare industry—he was approved on a party-line vote.⁵ Mr. Price spent his time at HHS working to gut the Affordable Care Act (ACA), reduce access to Medicaid, and undermine critical programs that promote Americans’ health and wellbeing. Ultimately, Mr. Price’s

¹ The White House, “Four Nominations and One Withdrawal Sent to the Senate Today” (November 14, 2017) (online at <https://www.whitehouse.gov/the-press-office/2017/11/14/four-nominations-and-one-withdrawal-sent-senate-today>).

² Rachel Roubein, “HHS nominee Azar to get Senate hearing Nov. 29,” *The Hill* (November 16, 2017) (online at <http://thehill.com/policy/healthcare/360746-hhs-nominee-azar-to-get-senate-hearing-nov-29>).

³ Peter Baker, Glenn Thrush, and Maggie Haberman, “Health Secretary Tom Price Resigns After Drawing Ire for Chartered Flights,” *New York Times* (September 29, 2017) (online at <https://www.nytimes.com/2017/09/29/us/politics/tom-price-trump-hhs.html>).

⁴ Amy Goldstein and Sean Sullivan, “Polarizing HHS nominee Tom Price Sworn in after Senate confirms on party-line vote,” *Chicago Tribune* (February 10, 2017) (online at <http://www.chicagotribune.com/news/nationworld/ct-tom-price-health-secretary-confirmation-20170209-story.html>).

⁵ Robert Pear, “Tom Price’s Heated Hearing Is Unlikely to Derail Is Nomination,” *New York Times* (January 24, 2017) (online at <https://www.nytimes.com/2017/01/24/us/politics/tom-price-nominee-secretary-of-health-and-human-services.html>); Jayne O’Donnell, “New stock questions plague HHS nominee Tom Price as confirmation vote nears,” *USA Today* (February 8, 2017) (online at <https://www.usatoday.com/story/news/politics/2017/02/08/new-stock-questions-plague-hhs-nominee-tom-price/97555796/>); “How Senators Voted on Tom Price for Health and Human Services Secretary,” *New York Times* (February 10, 2017) (online at <https://www.nytimes.com/interactive/2017/02/10/us/politics/tom-price-confirmation-vote.html>).

disregard for American taxpayers cost him his job: after spending hundreds of thousands of dollars on unnecessary chartered flights, he was forced to resign on September 29, 2017.⁶

As a member of the HELP Committee, I am deeply committed to developing an informed and complete assessment of your suitability to lead the Department of Health and Human Services. The scheduled nomination hearing will offer me only limited time to question you directly about your qualifications and your views on important policy questions related to HHS's mission. Therefore, I am writing today to request information to help me better assess your suitability for the position of HHS Secretary.

As a former General Counsel and Deputy Secretary at HHS,⁷ you are undoubtedly aware of the Department's mission to "enhance and protect the health and well-being of all Americans" by "providing for effective health and human services and fostering advances in medicine, public health, and social services."⁸ The Department's work includes critical research conducted by the National Institutes of Health ("NIH") and Centers for Disease Control ("CDC"). HHS also oversees the Food and Drug Administration ("FDA"), which regulates the safety of our nation's drugs, foods, and medical devices. It oversees the Medicare and Medicaid programs, which provide health care to millions of low-income, disabled, and elderly Americans.⁹

In announcing your nomination, the President promised that you would be "a star for better healthcare and lower drug prices!"¹⁰ I have several concerns about your ability to carry out the President's promises.

I am concerned that your tenure as a pharmaceutical executive may attenuate your interest in working to provide the American people with "lower drug prices." From 2007 through 2017, you worked at pharmaceutical company Eli Lilly, including serving as President of Lilly USA—the company's largest affiliate—for five years.¹¹ Though you appear to understand that "patients are paying too much for drugs," you also oppose common-sense interventions that would address high drug costs. You have described the rising cost of drugs as a problem "for insurance and pharma to work together to solve as opposed to the government"¹² and have

⁶ Juliet Eilperin, Amy Goldstein, and John Wagner, "HHS Secretary Tom Price resigns amid criticism for taking charter flights at taxpayer expense," *Washington Post* (September 29, 2017) (online at https://www.washingtonpost.com/news/post-politics/wp/2017/09/29/trump-to-decide-friday-night-whether-to-fire-hhs-secretary-price/?utm_term=.f3dd7f12aebb).

⁷ "Alex Azar," LinkedIn (accessed November 20, 2017) (online at <https://www.linkedin.com/in/azaralex/>).

⁸ U.S. Department of Health and Human Services, "About HHS" (online at <https://www.hhs.gov/about/index.html>).

⁹ U.S. Department of Health and Human Services, "HHS Agencies & Offices" (online at <https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html>).

¹⁰ President Donald J. Trump, @realDonaldTrump, "Happy to announce, I am nominating Alex Azar to be the next HHS Secretary. He will be a star for better healthcare and lower drug prices!" *Twitter* (November 13, 2017) (online at <https://twitter.com/realDonaldTrump/status/930087113764327424>).

¹¹ Juliet Eilperin and Amy Goldstein, "Trump picks Alex Azar to lead Health and Human Services," *Washington Post* (November 13, 2017) (online at https://www.washingtonpost.com/national/health-science/trump-picks-alex-azar-to-lead-the-health-and-human-services-department/2017/11/13/ad6a4e16-c408-11e7-84bc-5e285c7f4512_story.html?utm_term=.4f402b6ab5f7); "Alex Azar," LinkedIn (accessed November 20, 2017) (online at <https://www.linkedin.com/in/azaralex/>).

¹² Michelle Maskaly, "Former Pharmaceutical Executive Talks Drug Pricing, Future of Sales Reps," *Pharmaceutical Executive* (May 12, 2017) (online at <http://www.pharmexec.com/former-pharmaceutical-executive-talks-drug-pricing-future-sales-reps>).

labeled the efforts of European countries to reduce drug prices as “radical price controls.”¹³ Some health care analysts see your nomination as “a clear positive for the pharma sector” and believe you will “continue to pursue relatively pharma-friendly approaches to drug pricing.”¹⁴ Your track record at Eli Lilly further calls into question your commitment to reducing consumer costs. Under your leadership, Eli Lilly increased the cost of its insulin product Humulin R U-500 by 325% over a five-year period.¹⁵ The company’s insulin pricing practices are currently under investigation.¹⁶

Furthermore, your outspoken criticism of the ACA—at a time when bipartisan healthcare leadership is so sorely needed—calls into question your ability to provide Americans with “better healthcare.” You have opposed the Affordable Care Act and, in recent months, have ignored and denied the Trump Administration’s efforts to undermine it. In February, for example, you stated, “Obamacare is failing completely on its own terms...no one, nobody impacted it from the outside.”¹⁷ You apparently failed to take note of the Trump Administration’s efforts—including the slashing of the ACA’s advertising budget—to undermine the law.¹⁸ And in May, you described the ACA as “circling the drain” and said there were “fairly few levers the government can do...to try to stabilize this fundamentally broken system.”¹⁹ Your remarks are disturbing, given that, if confirmed as HHS Secretary, you would be responsible for implementing and stabilizing key pieces of the ACA.

The remainder of this letter contains a series of questions that will help me better understand how you, as HHS Secretary, would tackle the critical healthcare issues facing our nation today. I ask that you come to the hearing prepared to answer the questions I raise in today’s letter, and that you provide me with written answers to all questions by December 1, 2017. I also plan to submit additional written questions for the record following your hearing before the HELP Committee.

AFFORDABLE CARE ACT

Over the past eleven months, the Trump Administration, including the Department of Health and Human Services, has carried out a sustained campaign aimed at reducing access to health

¹³ Adam Cancryn and Sarah Karlin-Smith, “Trump picks ex-pharma executive Azar to lead HHS,” *Politico* (November 13, 2017) (online at <https://www.politico.com/story/2017/11/13/alex-azar-hhs-secretary-trump-244837>).

¹⁴ Bob Herman, “Trump’s HHS pick unlikely to crack down on drug prices,” *Axios* (November 14, 2017) (online at <https://www.axios.com/alex-azars-industry-history-shapes-health-care-positions-2509129076.html>); Bob Herman, @bobjherman, “In case there was any doubt, Wall St. is thrilled about Azar as the HHS pick,” *Twitter* (November 14, 2017) (online at <https://twitter.com/bobjherman/status/930451580851245056>).

¹⁵ Sarah Karlin-Smith, “Trump’s HHS secretary nominee boosted drug prices while at Eli Lilly,” *Politico* (November 14, 2017) (online at <https://www.politico.com/story/2017/11/14/alex-azar-eli-lilly-drug-prices-244888>).

¹⁶ Alex Kacik, “Two states launch investigation into Eli Lilly’s insulin pricing,” *Modern Healthcare* (May 1, 2017) (online at <http://www.modernhealthcare.com/article/20170501/NEWS/170509990>).

¹⁷ Dan Mangan, “Trump nominates former drug company executive Alex Azar as next Health and Human Services secretary,” *CNBC* (online at <https://www.cnn.com/2017/11/13/trump-nominates-alex-azar-as-next-hhs-secretary.html>).

¹⁸ Center on Budget and Policy Priorities, “Sabotage Watch: Tracking Efforts to Undermine the ACA” (online at <https://www.cbpp.org/sabotage-watch-tracking-efforts-to-undermine-the-aca>).

¹⁹ Fox Business, “Fmr. HHS Deputy Sec. Azar: ObamaCare is circling the drain” (May 11, 2017) (online at <http://video.foxbusiness.com/v/5430327620001/?sp=show-clips>).

insurance coverage provided through the Affordable Care Act exchanges and reducing the quality and affordability of that coverage. In January 2017, in the critical final week before the end of the annual sign-up period for health insurance, the Administration, ordered HHS to end on-line and social media advertisements encouraging enrollment. A subsequent investigation by the HHS Office of Inspector General (OIG), undertaken in response to a letter that Senator Murray and I wrote to the OIG, found that the decision to cancel ACA ads resulted in the waste of \$1.1 million taxpayer dollars. It also appears that the decision to cancel ads was made for primarily political reasons, with little regard for the impact of the cancellations on marketplace enrollment and premiums.²⁰

The Department also issued a “market stabilization” rule that dramatically shortened this year’s open enrollment period, from three months to six weeks, and has substantially reduced funding that helps individuals navigate the insurance sign-up process. The Administration cut off payments to insurers that help low-income families afford health care, a move that the Congressional Budget Office has estimated will cost the federal government \$194 billion over the next decade.²¹ And Department officials, including former Secretary Tom Price and CMS Administrator Seema Verma, have publicly supported proposals by Republicans in Congress to end the Medicaid expansion, take away health insurance from tens of millions Americans, and end protections for people with pre-existing conditions.

1. Should you be confirmed as HHS Secretary, what specific steps would you direct HHS to take in order to oversee and stabilize the ACA-established Marketplaces? What criteria would you use to measure your success in doing so?
2. You have been a vocal opponent of the ACA, yet will be responsible for implementing key portions of it. If confirmed as HHS Secretary, would you commit to assessing the impact on taxpayers of any effort to undermine the law? If a decision to undermine the ACA would result in a loss of taxpayer dollars, would you commit to preventing that decision from taking place?
3. Should you be confirmed as HHS Secretary, you would likely take office near the end of the open enrollment period for insurance for 2018. Over the course of 2017, the Trump Administration has taken multiple steps to undermine the efficacy of open enrollment, including massive cuts to ACA advertising and promotion. These steps threaten to reduce ACA enrollment, ultimately raising premiums and harming enrollees.²² As HHS Secretary, would you take steps to expand, rather than reduce, awareness of open enrollment? What steps would you take to reverse past policies to undercut open enrollment? Will you commit to restoring a three-month open enrollment period that

²⁰ U.S. Department of Health and Human Services, Office of the Inspector General, *Review of The Department of Health and Human Services (HHS) Cancellation of Marketplace Enrollment Outreach Efforts*, OIG-12-17-00290 (October 25, 2017) (online at <https://oig.hhs.gov/oei/reports/oei-12-17-00290.pdf>).

²¹ Congressional Budget Office, “The Effects of Terminating Payments for Cost Sharing Reductions” (August 2017) (online at <https://www.cbo.gov/system/files/115th-congress-2017-2018/reports/53009-costsharingreductions.pdf>).

²² Haeyoun Park, “We’re Tracking the Ways Trump is Scaling Back Obamacare. Here are 12.” *New York Times* (October 12, 2017) (online at https://www.nytimes.com/interactive/2017/10/12/us/trump-undermine-obamacare.html?_r=0).

allows Americans sufficient time to consider health insurance options and sign up for coverage?

4. Will you commit to funding advertisement and outreach efforts, and restoring funding for groups and organizations that work in local communities to facilitate enrollment?
5. If confirmed as HHS Secretary, will you advise the President to resume payments for the cost-sharing reduction (CSR) subsidies that help low-income families afford health care? If not, why not?

BEHAVIORAL HEALTH COVERAGE

According to 2015 data from the Substance Abuse and Mental Health Services Administration, over 18 percent of adults in the U.S. have some type of mental illness, yet less than half of these individuals receive mental health services.²³ Lack of insurance coverage and funding for mental health services are key causes of this gap in treatment. Mental health parity laws require that insurance coverage for behavioral health care services is equivalent to the coverage that insurers provide for physical health care services. However, surveys of beneficiaries and reports from patients tell a very different story. A 2015 survey from the National Alliance on Mental Illness (NAMI) found that over twice as many respondents had been denied coverage for mental health services as for general medical care.²⁴

Patients often find it difficult to navigate the process of appealing coverage denials and reporting problems. The lack of robust data regarding denial rates, reasons for denials, and insurance plan design further complicates enforcement of mental health parity. Last year, in response to a recommendation of President Obama’s Mental Health Parity and Substance Use Disorder Parity Task Force, the Department of Health and Human Services, working with the Departments of Labor and Treasury, released a parity portal website, to “help consumers navigate parity.” However, the “Mental Health and Addiction Insurance Help” website merely directs individuals to the various federal or state agencies who handle their claim and provides minimal information on parity laws. The Parity Task force said the original portal, “creates a starting point for future efforts to build out additional functionality such as complaint tracking.”²⁵

1. Given the importance of mental health parity laws in improving access to mental health and addiction treatment, do you commit to work with the Secretaries of Labor and the Treasury to increase enforcement of mental health parity laws?

²³ Center for Behavioral Health Statistics and Quality, SAMHSA, “Key Substance Use and Mental Health Indicators in the United States: Results from the 2015 National Survey on Drug Use and Health” (September 2017) (online at: <https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.htm>).

²⁴ National Alliance on Mental Illness (NAMI), “A Long Road Ahead – Achieving True Parity in Mental Health and Substance Use Care” (April 2015) (online at: <https://www.nami.org/About-NAMI/Publications-Reports/Public-Policy-Reports/A-Long-Road-Ahead/2015-ALongRoadAhead.pdf>).

²⁵ Mental Health and Substance Use Disorder Parity Task Force, *Final Report* (October 2016) (online at: <https://www.hhs.gov/sites/default/files/mental-health-substance-use-disorder-parity-task-force-final-report.pdf>); Department of Health and Human Services, “Mental Health and Addiction Insurance Help” (online at: <https://www.hhs.gov/mental-health-and-addiction-insurance-help>).

2. Would you advocate for increased audits of health plans to ensure they are complying with mental health parity laws?
3. Would you commit to work with the Secretaries of Labor and the Treasury to make the parity portal website more easily accessible to health care consumers seeking assistance with parity questions or complaints?
4. Will you commit to work with the Secretaries of Labor and the Treasury to expand the capacity of the parity portal (i.e. by adding functions such as complaint resolution and complaint tracking)?
5. What criteria will you use to measure your success in enforcing and improving compliance with mental health parity laws?

BIOMEDICAL RESEARCH FUNDING

Research funded by the National Institutes of Health (NIH) is critical to supporting the next generation of biomedical innovation. The NIH needs predictable, robust funding in order to conduct the research, development, and review of tomorrow's new discoveries and medical breakthroughs. The Commonwealth of Massachusetts relies on NIH funding to continue to pioneer scientific innovations: in FY2016 alone, the 190 NIH-funded institutions in the state received a total of 5,029 NIH grants.²⁶ The HHS Secretary is responsible for developing policy proposals and budgets that will provide support for current and future biomedical scientists, scientific innovations, and breakthroughs. In May 2017, President Trump released a draft budget that would have cut the NIH's budget by \$5.8 billion.²⁷ The President's budget met bipartisan opposition, and Congress ultimately rejected these dramatic cuts to biomedical research funding.²⁸

1. Do you agree that research funded by the NIH is critical to fueling advances in biomedical innovation?
2. Over the past 15 years, growth in the NIH budget has failed to keep pace with inflation and funding has declined in real terms. As HHS Secretary, what specific steps would you

²⁶ Federation of American Societies for Experimental Biology, "Massachusetts: National Institutes of Health State Funding Facts for FY2016" (online at <http://www.faseb.org/viewer.aspx?type=statefactsheet&id=209&nocache=636467849453183003&Name=Value-of-NIH-Funding-in-Massachusetts.pdf>).

²⁷ Joel Achenbach and Lena H. Sun, "Trump budget seeks huge cuts to science and medical research, disease prevention," *Washington Post* (May 23, 2017) (online at https://www.washingtonpost.com/news/to-your-health/wp/2017/05/22/trump-budget-seeks-huge-cuts-to-disease-prevention-and-medical-research-departments/?utm_term=.dde0f407d1f8); Ellen v. Sigal, "Trump's proposed budget would cripple the NIH and FDA," *STAT* (May 24, 2017) (online at <https://www.statnews.com/2017/05/24/trump-budget-nih-fda/>).

²⁸ Robert Pair, "Congress Rejects Trump Proposals to Cut Health Research Funds," *New York Times* (September 11, 2017) (online at <https://www.nytimes.com/2017/09/11/us/politics/national-institutes-of-health-budget-trump.html>).

take to restore investments in the NIH?

3. As HHS Secretary, would you commit to proposing NIH budgets that provide meaningful and sustainable funding for biomedical research?

DRUG PRICING

Increases in prescription drug costs continue to affect patients, who often struggle financially to afford necessary medications. Nationwide, prescription drug costs grew by 9 percent in 2015. Although this growth rate was lower than the 12 percent growth rate record in 2014, prescription drugs still outpaced the spending growth of all other types of health services.²⁹ Government spending on drugs through federal programs, including Medicare, Medicaid, and TRICARE, has also risen, creating costs for patients and taxpayers. A recent *Wall Street Journal* analysis found that the median out-of-pocket cost for a drug purchased by Medicare Part D beneficiaries was \$117, up almost 50% from 2011.³⁰ Prescription drugs accounted for about 14 percent of health care spending in Massachusetts in 2015 – one-third of total health care spending growth that year.³¹

1. You have been described as “oppos[ing] government intervention on drug prices,”³² yet the President has also pledged that if confirmed as HHS Secretary, you would be “a star for [. . .] lower drug prices!”³³ What specific steps will you take as HHS Secretary to lower the out-of-pocket costs paid by individuals using prescription drugs?
2. Do you agree with the President’s recent statement that drug companies are “getting away with murder”?³⁴
3. President Trump has expressed support for the government negotiating drug prices under Medicare, and the White House has noted that he is committed to using “his skills as a businessman to drive [prices] down.”³⁵ Do you agree with President Trump’s support for

²⁹ Center for Medicare and Medicaid Services, “National Health Expenditures 2015 Highlights” (online at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf>).

³⁰ Joseph Walker, “High-Price Drugs Raise Costs for Seniors in Medicare Part D,” *The Wall Street Journal* (May 29, 2017) (online at: <https://www.wsj.com/articles/high-priced-drugs-raise-costs-for-seniors-in-medicare-part-d-1496055603>).

³¹ Massachusetts Health Policy Commission, Annual Health Care Cost Trends Report 2016 (February 2017) (online at: <http://www.mass.gov/anf/budget-taxes-and-procurement/oversight-agencies/health-policy-commission/publications/2016-cost-trends-report.pdf>).

³² Anna Edney, Jared S. Hopkins, and Natasha Rausch, “Drug Costs in the Spotlight with Trump’s Pick for Health Secretary,” *Bloomberg* (November 14, 2017) (online at: <https://www.bloomberg.com/news/articles/2017-11-14/trump-health-pick-has-blamed-health-plans-pbms-for-drug-costs>).

³³ President Donald J. Trump, @realDonaldTrump, “Happy to announce, I am nominating Alex Azar to be the next HHS Secretary. He will be a star for better healthcare and lower drug prices!” *Twitter* (November 13, 2017) (online at <https://twitter.com/realDonaldTrump/status/930087113764327424>).

³⁴ Sarah Karlin-Smith, “Trump Renews Attacks on High Drug Prices,” *Politico* (October 16, 2017) (online at: <https://www.politico.com/story/2017/10/16/trump-attacks-high-drug-prices-243836>).

³⁵ Alison Kodak, “Medicare Should Leverage Buying Power to Pull Down Drug Prices, White House Says,” NPR (February 7, 2017) (online at: <https://www.npr.org/sections/health-shots/2017/02/07/513945538/white-house-says-medicare-should-leverage-its-buying-power-to-pull-down-drug-pri>).

allowing the government to negotiate for lower Medicare drug prices? If so, what specific steps would you take to carry out this policy?

4. Which Congressional proposals dealing with Medicare drug prices do you believe would be most effective at incentivizing value and positive outcomes?

HEALTHCARE FOR LGBTQ INDIVIDUALS

As HHS Secretary, you would be responsible for “enhance[ing] and protect[ing] the health and well-being of all Americans”—including LGBTQ citizens. Over the course of 2017, I have grown increasingly concerned with the Department’s commitment to promoting LGBTQ health.

President Trump has appointed a number of high-level Department employees who are outspokenly opposed to LGBTQ individuals. The HHS Assistant Secretary of Public Affairs, for example, has claimed that LGBTQ individuals are “wrestling with a disorder,” and has been connected to statements describing transgender individuals as “crazy” “creatures” who “take a meat cleaver to [their] manhood.”³⁶

Each year, HHS is required to develop and solicit public comment on a “strategic plan” for the agency. In September 2017, HHS released its Draft Strategic Plan for 2018-2022.³⁷ The Draft Strategic Plan included a series of concerning omissions—in particular, it failed to reference Section 1557 of the ACA, the “first federal civil rights law to prohibit sex discrimination in health care,” and LGBTQ individuals as a priority population for the Department.³⁸ This omission comes in the wake of HHS’ decision, earlier this year, to remove language from its Office of Civil Rights website clarifying that discrimination based on gender identify and sex stereotyping constitutes discrimination on the basis of sex.³⁹ In addition, HHS has taken multiple steps to limit data collection on LGBTQ individuals.

1. Do you believe that LGBTQ individuals deserve the same rights and access to health care as other American citizens, regardless of their sexual orientation or gender identity?
2. As HHS Secretary, what steps would you take to prevent individual employees’ opposition to LGBTQ rights from harming the health and wellbeing of LGBTQ citizens?

³⁶ Transgender Legal Defense and Education Fund, “Transgender Legal Defense Debates Family Research Council” (November 13, 2006) (online at <https://www.youtube.com/watch?v=REZ4NuLmm-k>).

³⁷ U.S. Department of Health and Human Services, “HHS Invites Public Comment on Draft 2018-2022 Strategic Plan” (October 19, 2017) (online at <https://www.hhs.gov/hepatitis/blog/2017/10/19/hhs-invites-public-comment-draft-2018-2022-strategic-plan.html>).

³⁸ Steve Lee, “Civil rights and health advocates express strong concerns about HHS’s draft strategic plan,” *LGBT Weekly* (November 15, 2017) (online at <http://lgbtweekly.com/2017/11/15/civil-rights-and-health-advocates-express-strong-concerns-about-hhss-draft-strategic-plan/>).

³⁹ See Letter from Senate Democrats to Secretary Tom Price (August 15, 2017) (online at https://www.help.senate.gov/imo/media/doc/20170815_August%201557%20Letter.pdf).

3. As HHS Secretary, would you make the healthcare of LGBTQ individuals a priority, including but not limited to placing LGBTQ individuals' needs into the Department's Strategic Plan?
4. As HHS Secretary, would you commit to protecting LGBTQ individuals from sex discrimination, including through aggressive enforcement of Section 1557 of the ACA?
5. What additional steps would you take, as HHS Secretary, to prioritize the health of LGBTQ Americans?

HEALTHCARE FOR WOMEN

In addition to programs designed to promote general health and wellbeing, HHS oversees a number of programs specifically targeted to improve women's reproductive and maternal health. The Office of Adolescent Health ("OAH"), for example, oversees the Department's Teen Pregnancy Prevention ("TPP") Program, a grant program designed to reduce rates of teen pregnancy.⁴⁰ The Office of Population Affairs ("OPA"), meanwhile, administers the Title X Family Planning Program ("Title X"), which provides millions of low-income Americans with basic reproductive healthcare.⁴¹ The Health Resources and Services Administration ("HRSA") uses evidence-based standards to establish which preventive services—like birth control—women's insurance plans must cover with no co-pay⁴², while other programs, like the Strong Start for Mothers and Newborns Initiative, aims to "reduce preterm births and improve outcomes for newborns and pregnant women."⁴³ As HHS Secretary, you would be responsible for managing and administering these programs.

HHS and Fact-Based Women's Health Policy

The expertise of medical experts, along with fact- and evidence-based programs, are critical to the successful implementation of health policy at HHS. Over the course of this year, I have been deeply disturbed by the caliber of some of President Trump's appointees at the Department—some of whom are unable to discern between fact and fiction in the realm of women's health policy.

The head of OPA, for example, has publicly stated that "contraception doesn't work" and that "[t]here...is no evidence to support" the claim that contraceptive use "reduce[s] the

⁴⁰ U.S. Department of Health and Human Services, Office of Adolescent Health, "About the Teen Pregnancy Prevention (TPP) Program" (online at <https://www.hhs.gov/ash/oah/grant-programs/teen-pregnancy-prevention-program-tpp/about/index.html>).

⁴¹ U.S. Department of Health and Human Services, Office of Population Affairs, "Title X Family Planning" (online at <https://www.hhs.gov/opa/title-x-family-planning/index.html>).

⁴² Kaiser Family Foundation, "Preventive Services Covered by Private Health Plans under the Affordable Care Act" (August 2015) (online at <http://files.kff.org/attachment/preventive-services-covered-by-private-health-plans-under-the-affordable-care-act-fact-sheet>).

⁴³ Centers for Medicare & Medicaid Services, "Strong Start for Mothers and Newborns Initiative: General Information" (online at <https://innovation.cms.gov/initiatives/strong-start/>).

incidence of abortion.”⁴⁴ There is, in fact, a plethora of scientific evidence confirming that contraception prevents pregnancy⁴⁵ and reduces the incidence of abortion.⁴⁶ Dr. Charmaine Yoest, the Department’s Assistant Secretary for Public Affairs believes that abortion procedures cause breast cancer—which the National Cancer Institute, the American Congress of Obstetricians and Gynecologists, and the American Cancer Society have “rejected, based on an abundance of research.”⁴⁷ E. Scott Lloyd, head of the Department’s Office of Refugee Resettlement, insists that “contraceptives are the cause of abortion,”⁴⁸ which, again, is objectively false. Even former HHS Secretary Price asserted that “there’s not one” woman in the country who struggled to purchase birth control prior to the passage of the Affordable Care Act—contrary to the experience of millions of women.⁴⁹

As the head of HHS, it is critical that you understand, respect, and build policies based on scientific consensus—not fringe pseudoscience.

1. Do you agree that all FDA-approved contraception methods—including but not limited to sterilization, the IUD, the implant, the shot, the pill, the patch, the vaginal ring, and the male and female condom—prevent pregnancy when used correctly?
2. Do you agree that contraceptive use is associated with a decline in abortion rates?
3. Do you agree that contraceptive devices—including the IUD—are not abortifacients?
4. Do you agree that all reproductive-health-related policies (including policies relating to contraception and abortion) should be based on the fact- and evidence-based conclusions of the medical and scientific communities?
5. As HHS Secretary, what would you do to ensure that existing employees of HHS—particularly those in leadership positions—who hold fringe beliefs about reproductive health do not allow their unsubstantiated views to affect HHS policies?

⁴⁴ Hannah Levintova, “Trump Just Picked a Contraception Skeptic to Head Federal Family Planning Efforts,” *Mother Jones* (May 1, 2017) (online at <http://www.motherjones.com/politics/2017/05/donald-trump-hhs-teresa-manning-contraception-abortion/#>).

⁴⁵ See U.S. Food and Drug Administration, “Birth Control Guide” (online at <https://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM517406.pdf>).

⁴⁶ Joerg Dreweke, “New Clarity for the U.S. Abortion Debate: A Steep Drop in Unintended Pregnancy Is Driving Recent Abortion Declines,” *Guttmacher Institute* (March 18, 2016) (online at <https://www.guttmacher.org/gpr/2016/03/new-clarity-us-abortion-debate-steep-drop-unintended-pregnancy-driving-recent-abortion>).

⁴⁷ Emily Bazelon, “New Soldiers for Trump’s Anti-Abortion Army,” *New York Times* (May 2, 2017) (online at <https://www.nytimes.com/2017/05/02/opinion/abortion-charmaine-yoest-teresa-manning.html>).

⁴⁸ Rachel Siegel, “The Trump official who tried to stop a detained immigrant from getting an abortion,” *Washington Post* (October 26, 2017) (online at https://www.washingtonpost.com/news/post-nation/wp/2017/10/26/the-trump-official-who-tried-to-stop-a-detained-immigrant-from-getting-an-abortion/?utm_term=.64921229598f).

⁴⁹ Olag Khazan, “Tom Price: ‘Not One’ Woman Struggled to Afford Birth Control,” *The Atlantic* (November 29, 2016) (online at <https://www.theatlantic.com/health/archive/2016/11/tom-price-not-one-woman-cant-afford-birth-control/509003/>).

6. Should you find that Administration policies on reproductive health directly conflict with science, what steps will you take to ensure that the American people are not harmed by these policies?

Contraception and the Affordable Care Act

Prior to the ACA, one in five women reported that they “put off or postponed preventive services” due to cost.⁵⁰ Section 2713 of the Affordable Care Act requires qualified health plans to cover “preventive services” for women as an essential health benefit with no cost-sharing. The Secretary of HHS has the authority to define these preventive services for women, based on the evidence-based recommendations of the Health Resources and Services Administration (HRSA). Current HRSA recommendations include contraception as a preventive service. However, in October 2017, HHS issued two interim final rules that allow employers to refrain from offering birth control coverage to their employees, should they have a religious or moral objection to doing so.⁵¹

1. Do you believe that HRSA should continue to define “preventive services” for women to include all FDA-approved forms of contraception?
2. The interim final rules went into effect immediately, yet are open for public comment until December 5, 2017. A cursory scan of already-submitted comments to HHS, Treasury, and the Department of Labor reveals that thousands of Americans oppose the new rules. As HHS Secretary, what steps would you take to address the commenters’ concerns?
3. What steps would you take to expand access to birth control? What steps would you take to ensure that women impacted by the new interim rules can access contraception in spite of their employers’ opposition?

Teen Pregnancy Prevention Program

Since the implementation of Title X in 2010, teen childbearing has declined by 35% nationwide, suggesting that the program is “highly effective.”⁵² However, in July 2017, the Office of Adolescent Health announced that it would cut short funds for all TPP grants.⁵³ OAH provided no rationale for its decision. Earlier this month, OAH announced a “new research and evaluation collaboration” under the auspices of TPP designed to “improve teen pregnancy

⁵⁰ Kaiser Family Foundation, “Preventive Services for Women Covered by Private Health Plans under the Affordable Care Act” (December 20, 2016) (online at <http://files.kff.org/attachment/Fact-Sheet-Preventive-Services-for-Women-Covered-by-Private-Health-Plans-under-the-Affordable-Care-Act>).

⁵¹ U.S. Department of Health and Human Services, “Trump Administration Issues Rules Protecting the Conscience Rights of All Americans” (October 6, 2017) (online at <https://www.hhs.gov/about/news/2017/10/06/trump-administration-issues-rules-protecting-the-conscience-rights-of-all-americans.html>).

⁵² Christine Dehlendorf, “Successful teen pregnancy prevention program threatened by funding cuts,” *STAT News* (April 20, 2017) (online at <https://www.statnews.com/2017/04/20/successful-teen-pregnancy-prevention-program-threatened-funding-cuts/>).

⁵³ Christine Dehlendorf, “Successful teen pregnancy prevention program threatened by funding cuts,” *STAT News* (April 20, 2017) (online at <https://www.statnews.com/2017/04/20/successful-teen-pregnancy-prevention-program-threatened-funding-cuts/>).

prevention and sexual risk avoidance.”⁵⁴ “Sexual risk avoidance” is a euphemism for “abstinence-only”⁵⁵—an ineffective form of sex education that does not reduce the rates of teen pregnancy.⁵⁶

1. As HHS Secretary, would you direct the Department to implement evidence-based, effective pregnancy prevention programs that are proven to reduce teen pregnancy rates? Would you take steps to restore the Title X grants that OAH recently cut short?
2. The scientific consensus on “sexual risk avoidance,” or abstinence-only, programs, is that they are ineffective. Do you agree with this consensus?
3. Do you believe American taxpayers should fund ineffective health programs?
4. As HHS Secretary, what steps would you take to ensure that other pregnancy prevention programs within the Department, such as the Personal Responsibility Education Program (“PREP”), are not co-opted by “sexual risk avoidance” programs at the expense of evidence-based pregnancy prevention?

Title X Family Planning Program

The Title X Family Planning Program funds basic reproductive health services—including cancer screenings, STI testing, and contraception—for over 4 million low-income Americans every year.⁵⁷ Title X does not provide funds for abortion services.

Though it was originally established with bipartisan support, Title X has faced increased attacks from Republicans in recent years. Some states have attempted to exclude reproductive health centers that also provide abortion services from receiving Title X funds—a process that the Trump Administration made easier this year⁵⁸ when it nullified an HHS rule clarifying that Title X recipients cannot be barred from receiving funds “on bases unrelated to their ability to provide Title X services effectively.”⁵⁹ In addition, a policy memo from the White House’s Domestic Policy Council reveals that the Trump Administration would like to “cut [the budget of

⁵⁴ U.S. Department of Health and Human Services, Office of Adolescent Health, “HHS Announces New Efforts to Improve Teen Pregnancy Prevention & Sexual Risk Avoidance Programs” (November 6, 2017) (online at <https://www.hhs.gov/ash/oah/news/news-releases/new-sexual-risk-avoidance-programs/index.html>).

⁵⁵ Mark Peters, “Euphemism: sexual risk avoidance,” *Boston Globe* (June 23, 2017) (online at <https://www.bostonglobe.com/ideas/2017/06/23/euphemism-sexual-risk-avoidance/cowYjFTOcIS7hmd0wtm64O/story.html>).

⁵⁶ John Santelli, “Abstinence-only education doesn’t work. We’re still funding it.” *Washington Post* (August 21, 2017) (online at https://www.washingtonpost.com/news/posteverything/wp/2017/08/21/abstinence-only-education-doesnt-work-were-still-funding-it/?utm_term=.6d87ac444f17).

⁵⁷ Planned Parenthood Action Fund, “Title X: America’s Family Planning Program” (online at <https://www.plannedparenthoodaction.org/issues/health-care-equity/title-x>).

⁵⁸ Colin Dwyer, “Trump Signs Law Giving States Option to Deny Funding for Planned Parenthood,” *NPR* (April 13, 2017) (online at <http://www.npr.org/sections/thetwo-way/2017/04/13/523795052/trump-signs-law-giving-states-option-to-deny-funding-for-planned-parenthood>).

⁵⁹ Health and Human Services Department, *Compliance With Title X Requirements by Project Recipients in Selecting Subrecipients* (December 19, 2016) (online at <https://www.federalregister.gov/documents/2016/12/19/2016-30276/compliance-with-title-x-requirements-by-project-recipients-in-selecting-subrecipients>).

Title X] in half at least” in order to fund “childcare programs, or new fertility awareness programs for adolescents.”⁶⁰

1. Do you believe that states should be able to deny Title X funding to health providers that meet program criteria for providing reproductive health services?
2. As HHS Secretary, would you restore Department policies ensuring that states do not deny Title X funding to health providers for reasons other than their ability to provide reproductive health services?
3. An analysis of Title X in the *American Journal of Public Health* found that the program would require “approximately \$737 million...to provide family planning services to all uninsured low-income women of reproductive age in the United States.”⁶¹ In FY 2017, Title X received just \$286.5 million, or roughly 40% of the budget necessary to meet the need for Title X services.⁶²
 - a. Do you agree with the Trump Administration that the Title X budget should be “cut in half”?
 - b. As HHS Secretary, would you advocate for increased funding for Title X?
4. According to a Domestic Policy Council memo, the Trump Administration hopes to prioritize “fertility awareness programs” in lieu of the existing Title X program. Fertility awareness is a behavioral contraceptive method in which a woman tracks her menstruation, cervical mucus, and/or basal body temperature to determine when she is most fertile, allowing her to avoid sexual intercourse during her peak fertility. The fertility awareness method, without dual use of a barrier contraceptive, does not protect against sexual transmitted infections (STIs).⁶³ The fertility awareness method is more complicated and time consuming than other forms of birth control, such as the pill and the IUD, and is also less effective: for every 100 women relying on the fertility awareness method each year, 12-24 women will become pregnant—compared to 9 pill users and 1 IUD user.⁶⁴

⁶⁰ Brian Beutler, “Leaked Memo Reveals White House Wish List,” *Crooked* (October 19, 2017) (online at <https://crooked.com/article/leaked-memo-reveals-white-house-wish-list/>).

⁶¹ National Family Planning & Reproductive Health Association, “Title X: Budget and Appropriations” (online at https://www.nationalfamilyplanning.org/title-x_budget-appropriations); Euna M. August et al., “Projecting the Unmet Need and Costs for Contraception Services After the Affordable Care Act,” *American Journal of Public Health* (February 2016) (online at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4985850/>).

⁶² National Family Planning & Reproductive Health Association, “Title X: Budget and Appropriations” (online at https://www.nationalfamilyplanning.org/title-x_budget-appropriations).

⁶³ American Congress of Obstetricians and Gynecologists, “Fertility Awareness-Based Methods of Family Planning” (online at <https://www.acog.org/Patients/FAQs/Fertility-Awareness-Based-Methods-of-Family-Planning#what>).

⁶⁴ American Congress of Obstetricians and Gynecologists, “Fertility Awareness-Based Methods of Family Planning” (online at <https://www.acog.org/Patients/FAQs/Fertility-Awareness-Based-Methods-of-Family-Planning#what>); U.S. Food and Drug Administration, “Birth Control Guide” (online at <https://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM517406.pdf>).

- a. Do you believe that HHS should devote significant time and resources to promoting the fertility awareness method, at the expense of more effective contraceptives?
- b. Do you believe that women who access reproductive health services through government programs should have access to the full range of contraceptive devices and methods, with the freedom to choose which method works best for them?

MEDICAID

The Medicaid program covers over 70 million low-income Americans, including 6 million low-income elderly Americans, 40% of all children, 49% of pregnant women, and 30% of all non-elderly, disabled adults.⁶⁵ Since taking office, President Trump has supported legislation that would cut Medicaid by more than \$700 billion, converting it to a per capita cap or block grant system.⁶⁶ His budget proposal for fiscal year 2018 (FY18) also proposed an additional cut to Medicaid of over \$600 billion.⁶⁷ You have also expressed support for block granting the Medicaid program, saying, "I think there's a lot to commend a block grant approach."⁶⁸ Yet analysts have indicated that Medicaid block grants would "institute deep cuts to federal funding" and "threaten benefits for tens of millions of low-income families, senior citizens, and people with disabilities."⁶⁹ In order to cope with their drastically reduced federal funding, "states would likely have no choice but to institute draconian cuts to eligibility, benefits, and provider payments."⁷⁰

⁶⁵ Kaiser Family Foundation, "Medicaid Pocket Primer" (January 3, 2017) (online at <http://kff.org/medicaid/factsheet/medicaid-pocket-primer/>); Julia Paradise, Barbara Lyons, and Diane Rowland, "Medicaid at 50: People with Disabilities," Kaiser Family Foundation (May 6, 2015) (online at <http://kff.org/report-section/medicaid-at-50-people-with-disabilities/>); Center on Budget and Policy Priorities, "Policy Basics: Introduction to Medicaid" (August 16, 2016) (online at <http://www.cbpp.org/research/health/policy-basics-introduction-to-medicaid>).

⁶⁶ Philip Bump, "By 2026, Annual Medicaid Cuts under the Senate Health-Care Replacement Plan are Steeper than Under Repeal," *Washington Post* (July 19, 2017) (online at: https://www.washingtonpost.com/news/politics/wp/2017/07/19/by-2026-annual-medicaid-cuts-under-the-senate-health-care-replacement-plan-are-steeper-than-under-repeal/?utm_term=.27c6f093a793); Danielle Kurzleben, "GOP Health Plan Would Leave 23 Million More Uninsured, Budget Office Says," *NPR* (May 24, 2017) (online at: <http://www.npr.org/2017/05/24/529902300/cbo-republicans-ahca-would-leave-23-million-more-uninsured>).

⁶⁷ Iris J. Lav, Michael Leachman, "The Trump Budget's Massive Cuts to State and Local Services and Programs," *Center on Budget and Policy Priorities* (June 13, 2017) (online at: <https://www.cbpp.org/research/state-budget-and-tax/the-rump-budgets-massive-cuts-to-state-and-local-services-and>).

⁶⁸ "Alex Azar: Should Medicaid Be Turned Into a Block Grant Program?" Zetema Project (February 23, 2017) (online at: <https://www.youtube.com/watch?v=ePzgW30qUuc>).

⁶⁹ Edwin Park, "Medicaid Block Grant Would Slash Federal Funding, Shift Costs to States, and Leave Millions More Uninsured," Center on Budget and Policy Priorities (November 30, 2016) (online at: <https://www.cbpp.org/research/health/medicaid-block-grant-would-slash-federal-funding-shift-costs-to-states-and-leave>).

⁷⁰ Edwin Park, "Medicaid Block Grant Would Slash Federal Funding, Shift Costs to States, and Leave Millions More Uninsured," Center on Budget and Policy Priorities (November 30, 2016) (online at: <https://www.cbpp.org/research/health/medicaid-block-grant-would-slash-federal-funding-shift-costs-to-states-and-leave>).

As HHS Secretary, you will be responsible for addressing the concerns and advancing the interests of America's seniors and people with disabilities.

1. Do you agree that Medicaid plays an essential role in ensuring that seniors and people with disabilities can get access to affordable high-quality services that allow them to live independently at home and in their communities?
2. Do you agree that hundreds of billions of dollars in cuts to Medicaid would have a negative impact on the ability of seniors and people with disabilities to access health care?
3. The Center for Medicare and Medicaid Innovation ("CMMI"), a research center under the Centers for Medicare and Medicaid Services ("CMS") has authority to test different approaches of paying for Medicare and Medicaid coverage. You have expressed support for using CMMI's administrative authorities to test Medicaid block grants.⁷¹ Can you reassure Americans that, as HHS Secretary, you will not use your administrative authorities under CMMI or any other HHS program to enact policies that result in reduced benefits or eligibility for Medicaid beneficiaries or increase their out-of-pocket costs?

OPIOID EPIDEMIC

The opioid epidemic is devastating communities across the country and requires an all hands on deck approach. Opioids caused more than 33,000 deaths in 2015, an average of 91 deaths every day.⁷² In Massachusetts, more than 2,000 individuals died from opioid overdoses in 2016.⁷³ The epidemic continues to grow, with deadly consequences. In just three years, across the country overdose deaths related to synthetic opioids such as fentanyl, which is 50 to 100 times more powerful than morphine, grew by 264%.⁷⁴

The Department of Health and Human Services oversees 11 agencies that play a role in addressing the opioid epidemic. The Secretary must collaborate across federal agencies, and with state and local governments, the private sector, and international partners - key partners in tackling the opioid crisis.⁷⁵

⁷¹ "Alex Azar: Should Medicaid Be Turned Into a Block Grant Program?" Zetema Project (February 23, 2017) (online at: <https://www.youtube.com/watch?v=ePzgW30qUuc>).

⁷² "Opioid Overdose," *Centers for Disease Control and Prevention (CDC)*, (online at: <https://www.cdc.gov/drugoverdose/index.html>) (Accessed November 2, 2017); "Understanding the Epidemic," *CDC* (online at: <https://www.cdc.gov/drugoverdose/epidemic/index.html>) (Accessed November 2, 2017).

⁷³ Martha Bebinger, "Opioid Overdose Deaths In Mass. Reach Grim Milestone," *WBUR* (May 10, 2017) (online at: <http://www.wbur.org/commonhealth/2017/05/10/opioid-overdose-deaths-top-2000>)

⁷⁴ "Prescription Behavior Surveillance System (PBSS) Issue Brief," *CDC National Center for Injury Prevention and Control* (July 2017) (online at: <https://www.cdc.gov/drugoverdose/pdf/pbss/PBSS-Report-072017.pdf>).

⁷⁵ HHS Agencies & Offices (online at: <https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html>); U.S. Department of Health and Human Services Strategic Plan: Introduction (online at: <https://www.hhs.gov/about/strategic-plan/introduction/index.html>) (Accessed November 2, 2017).

On October 26, 2017, more than two months after initially saying he would declare the opioid crisis a national emergency, President Trump declared the opioid epidemic a national public health emergency under the Public Health Service Act (PHSA).⁷⁶ Under the PHSA, the Secretary of HHS's determination of a public health emergency expands their powers, to "take such action as may be appropriate to respond to the public health emergency, including making grants, providing awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder."⁷⁷ As HHS Secretary, you will be empowered to deliver on President Trump's promises, which have not yet included any commitment for the increased federal funds that experts on the front lines of this crisis have suggested we need.

Additionally, on November 1, the Commission on Combating Drug Addiction and the Opioid Crisis released a series of recommendations for the federal government and Congress to address this crisis. The majority of the 56 recommendations in the report will require the involvement and leadership of the HHS Secretary, including recommendations to "design and implement a wide-reaching, national multi-platform media campaign," to "remove reimbursement and policy barriers" to substance use disorder treatment, to "provide additional resources to the National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), and National Institute on Alcohol and Alcoholism (NIAAA)," and to "negotiate reduced pricing for all governmental units."⁷⁸

National Public Health Emergency

1. Will you commit to treating the opioid epidemic as a real emergency, including by working to secure increased funds for states and communities already on the front lines of this emergency?
2. Will you urge the President and other cabinet members to publicly call for a significant increase in federal funding to address this epidemic?
3. What specific actions will you take as HHS Secretary to fulfill the President's declaration of a national public health emergency on opioids?
4. What steps will you take to update and work with members of Congress on this emergency, and to ensure that HHS has the resources it needs to stem this epidemic?

⁷⁶ Julie Hirschfeld Davis, "Trump Declares Opioid Crisis a 'Health Emergency' but Requests No Funds," *The New York Times* (October 26, 2017) (online at: <https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html>); "Presidential Memorandum for the Heads of Executive Departments and Agencies," *White House Office of the Press Secretary* (October 26, 2017) (online at: <https://www.whitehouse.gov/the-press-office/2017/10/26/presidential-memorandum-heads-executive-departments-and-agencies>).

⁷⁷ 42 U.S.C. Sec. 247d, Public health emergencies (online at: <https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap6A-subchapII-partB-sec247d.pdf>); Public Health Emergency Declaration (online at: <https://www.phe.gov/Preparedness/legal/Pages/pheddeclaration.aspx>) (Accessed November 2, 2017).

⁷⁸ Recommendations of The President's Commission on Combating Drug Addiction and the Opioid Crisis (November 1, 2017) (online at: https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf).

5. How will you work with states like Massachusetts that have previously declared the opioid epidemic an emergency to learn about their efforts and share these lessons with other states?

Partial Fill

At the core of the opioid epidemic has been the overprescribing and misuse of addictive and dangerous prescription painkillers. CMS reported that generic Vicodin was prescribed to more Medicare beneficiaries than any other drug in 2013 – more than blood pressure medication, more than cholesterol medication, more than acid reflux medication.⁷⁹ The National Institute on Drug Abuse has estimated that over 70% of individuals who misuse prescription opioids get the medication from friends or relative, so reducing the amount of unused medications in the home is a powerful new tool to tackle prescription drug abuse.⁸⁰

The Comprehensive Addiction and Recovery Act, passed in July 2016, included a bipartisan provision that I worked on with Senator Capito, which empowers patients to talk to their physicians and pharmacists about partially filling their prescription medications in order to reduce the amount of unused opioids in circulation.⁸¹ This provision amended the Controlled Substances Act to allow partial filling of any Schedule II prescription, including painkillers such as OxyContin and Vicodin. For example, this means that when a patient goes to the pharmacy to pick up their opioid prescription, they can request that their pharmacist only fill enough of the prescription for a few days supply – and then, return to the pharmacy if pain persists to pick up the remainder of their prescription.

1. Do you believe that reducing the number of unused medications in the home is an important tool in tackling the misuse of prescription medications?
2. Would you commit to working with the Drug Enforcement Administration to address the overprescribing and misuse of addictive prescription medications, while still ensuring that patients who need pain medication can receive it?
3. How would you work with states, physicians, pharmacists, and patient groups to increase awareness about partial fill policies?

Fentanyl

In Massachusetts, there has been a clear shift from overdose deaths connected to prescription drugs and heroin to the increased use of the harmful synthetic opioid fentanyl. This has further contributed to this public health crisis and has created a significant challenge for our public health and safety officials. Recently, the CDC collaborated with the Massachusetts Department of Public Health and the Office of the Chief Medical Examiner to study fentanyl overdoses. The original study released in 2016 found that for opioid-related fatalities in the state in which it was

⁷⁹ “CMS Releases Prescriber-Level Medicare Data for First Time,” *Centers for Medicare & Medicaid Services* (April 30, 2016) (online at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-04-30.html>).

⁸⁰ National Institute on Drug Abuse fact sheet (online at: <https://www.drugabuse.gov/sites/default/files/poppingpills-nida.pdf>).

⁸¹ See S. 524: Comprehensive Addiction and Recovery Act of 2016 (online at <https://www.congress.gov/bill/114th-congress/senate-bill/524/text>).

possible to conduct a toxicology screen, 74% of individuals tested positive for fentanyl.⁸² As of November 2017, that percentage had increased to 81%. That study also noted, “the rate of heroin or likely heroin present in opioid-related deaths has been decreasing while the presence of fentanyl is still trending upward.”⁸³

1. What would you do to build on HHS’s efforts to address this specific component of the opioid epidemic?
2. How would you work with other federal agencies to improve surveillance and support the work of states dealing with significantly high rates of opioid overdoses due to illicitly produced fentanyl?
3. What steps would you take to address emerging trends in this crisis, such as the increased use of carfentanil?

Syringe Exchange Programs, Supervised Injection Facilities, and Infectious Diseases

Syringe exchange programs, also known as syringe services programs (SSPs), are locations where individuals can go to get sterile needles and syringes and safely dispose of used items, as well as get education on safer practices and treatment for other medical, social, or mental health needs. The public health benefits, including reduced risks for HIV and Hepatitis C, are clearly acknowledged by the NIH, CDC, and other scientific bodies.⁸⁴ In 2015, then-Governor Mike Pence responded to an HIV and HCV outbreak in Indiana by signing a law that allowed counties in Indiana to establish Syringe Service Programs.⁸⁵ Massachusetts has 14 successful syringe exchange programs, with the goal of getting people into treatment for addiction and other health issues.⁸⁶

The opioid epidemic has spurred increases in Hepatitis B and Hepatitis C infections.⁸⁷ In 2015, the CDC released data showing a nationwide increase in reported cases of Hepatitis C (HCV) – increases that indicate “a geographic intersection among opioid abuse, drug injecting,

⁸² Massachusetts Department of Public Health, “Data Brief: Opioid-related Overdose Deaths Among Massachusetts Residents” (November 2016) (online at <http://www.mass.gov/eohhs/docs/dph/stop-addiction/current-statistics/data-brief-overdose-deaths-nov-2016-ma-residents.pdf>).

⁸³ Massachusetts Department of Public Health, “Data Brief: Opioid-Related Overdose Deaths Among Massachusetts Residents (November 2017) (online at: <https://www.mass.gov/files/documents/2017/11/13/sec1-od%20deaths%20mass%20residents%20Nov-17.pdf>).

⁸⁴ “Syringe-Exchange Programs Are Part of Effective HIV Prevention,” National Institute on Drug Abuse, National Institutes of Health (December 1, 2016) (online at: <https://www.drugabuse.gov/about-nida/noras-blog/2016/12/syringe-exchange-programs-are-part-effective-hiv-prevention>). Syringe Services Programs, Centers for Disease Control and Prevention (online at: <https://www.cdc.gov/hiv/risk/ssps.html>) (last updated September 28, 2017).

⁸⁵ Megan Twohey, “Mike Pence’s Response to H.I.V. Outbreak: Prayer, Then a Change of Heart,” *New York Times* (August 7, 2016) (online at https://www.nytimes.com/2016/08/08/us/politics/mike-pence-needle-exchanges-indiana.html?_r=0).

⁸⁶ Jamie Ducharme, “DPH Seeks Money for More Mass. Needle Exchanges,” *Boston Magazine* (March 24, 2017) (online at: <http://www.bostonmagazine.com/health/2017/03/24/massachusetts-needle-exchanges/>).

⁸⁷ HEP, “The Intersection of the Opioid and Heroin Epidemic and Hepatitis” (May 17, 2016) (online at <https://www.hepmag.com/blog/intersection-opioid-heroin-epidemic-hepatitis>).

and HCV infection.”⁸⁸ And in 2016, the CDC announced the number of Americans infected with Hepatitis B (HCB) had significantly increased in the geographic areas most affected by the opioid epidemic.⁸⁹

Research has also shown benefits of Supervised Injection Facilities (SIFs), where people can use their own drugs, under medical supervision. Research indicates that SIFs can help reduce HIV and hepatitis transmission risks, prevent overdose deaths, and increase the number of people seeking out addiction treatment.⁹⁰

1. As HHS Secretary, would you commit to continued support for syringe exchange programs/syringe services programs?
2. HHS has developed guidance for health departments on how to request permission to use federal funds to support SSPs. Will you commit to retaining this guidance? Would you continue to share this guidance with states and work with states as they navigate this process?
3. Given the devastating effects of the opioid epidemic, including increased risks for Hepatitis transmission, would you commit to increasing your agencies support for syringe services programs to provide outreach and linkage-to-care to those most at risk and in need of HIV, Hepatitis, overdose, and addiction treatment services?
4. Would you commit to advocating for studying safe injection facilities as a tool in the fight against the opioid epidemic?

Expanded Access to Naloxone

Access to naloxone, a prescription drug meant to reverse an opioid overdose, saves lives. However, more could be done to expand access to naloxone. In August 2016, the FDA outlined the steps it was taking to ensure greater access to naloxone, including “helping manufacturers pursue approval of an OTC naloxone product, including helping to develop the package label that would be required for such a product.”⁹¹ The FDA indicated that it had created a model Drug Facts Label and accompanying pictogram that could provide consumers with necessary information about how to use naloxone safely, and was engaged in label comprehension testing of this model label.

⁸⁸ Centers for Disease Control and Prevention, “Increases in Hepatitis C Virus Infection Related to Injection Drug Use Among Persons Aged ≤30 Years — Kentucky, Tennessee, Virginia, and West Virginia, 2006–2012” (May 8, 2015) (online at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6417a2.htm>).

⁸⁹ Centers for Disease Control and Prevention, “Increases in Acute Hepatitis B Virus Infections—Kentucky, Tennessee, and West Virginia, 2006–2013” (January 29, 2016) (online at <https://www.cdc.gov/mmwr/volumes/65/wr/mm6503a2.htm>).

⁹⁰ Frakt, Austin, “JAMA Forum: Safe Injection Facilities Reduce Individual and Societal Harms,” JAMA (April 5, 2017) (online at: <https://newsatjama.jama.com/2017/04/05/jama-forum-safe-injection-facilities-reduce-individual-and-societal-harms/>)

⁹¹ Karen Mahoney, “FDA Supports Greater Access to Naloxone to Help Reduce Opioid Overdose Deaths,” FDA Voice (August 10, 2016) (online at: <https://blogs.fda.gov/fdavoices/index.php/2016/08/fda-supports-greater-access-to-naloxone-to-help-reduce-opioid-overdose-deaths/>).

1. As HHS Secretary, what steps would you take to work with your agencies, other federal departments, manufacturers, and other partners to expand access to naloxone?
2. Would you commit to supporting the FDA's ongoing work to develop and test a package label for an OTC naloxone product?

Marijuana

Medical marijuana has the potential to mitigate the effects of the opioid crisis. A 2017 *American Journal of Public Health* study, for example, studied Colorado's legalization of adult-use recreational marijuana and found that it resulted in almost one fewer opioid overdose death each month and determined that the "legalization of cannabis in Colorado was associated with short-term reductions in opioid-related deaths."⁹² This is consistent with other data from states that have developed laws for medical or recreational marijuana use.

1. As HHS Secretary, what would you do to further study this potential alternative to opioids?
2. Are you committed to implementing evidence-based policies regarding its use?
3. What steps will you take to improve our knowledge of the potential therapeutic benefits of marijuana when used for medical purposes?

Protecting Vulnerable Nursing Home Residents

There are an estimated 1.4 million Nursing Home Residents in the United States.⁹³ The Medicaid program is the primary payer for this care, paying for the care of 62% of these nursing home residents.⁹⁴ Providing high-quality care continues to be a challenge for many nursing homes; in fact, earlier this year, the HHS Inspector General found that there were dozens of cases of abuse and neglect in audited nursing homes, and that "CMS has inadequate procedures to ensure that incidents of potential abuse or neglect of Medicare beneficiaries residing in SNFs are identified and reported."⁹⁵

Congress has long been concerned about inadequate care in nursing homes, and the Affordable Care Act included a number of provisions designed to address deficiencies, improve staff training, and impose new penalties for nursing homes that violate quality of care requirements. But I have been concerned by recent actions by the Trump Administration to weaken rules put in place by President Obama to implement these new requirements. In June and October 2017, CMS revised policies to make it more difficult to impose civil monetary

⁹² Livingston, Barnett, Delcher, Wagenaar, "Recreational Cannabis Legalization and Opioid Related Deaths in Colorado, 2000-2015," *American Journal of Public Health* (October 11, 2017) (online at: <http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2017.304059?journalCode=ajph&>).

⁹³ Kaiser Family Foundation, *Medicaid's Role in Nursing Home Care* (June 2017) (<https://www.kff.org/infographic/medicaids-role-in-nursing-home-care/>).

⁹⁴ Kaiser Family Foundation, *Medicaid's Role in Nursing Home Care* (June 2017) (<https://www.kff.org/infographic/medicaids-role-in-nursing-home-care/>).

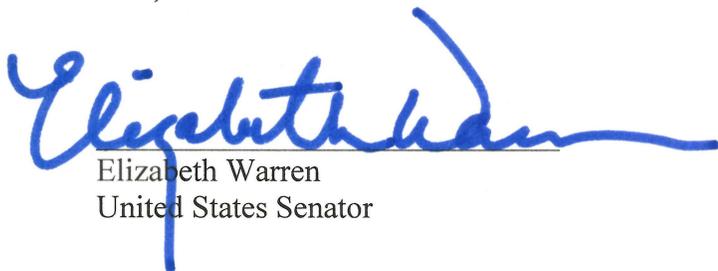
⁹⁵ HHS OIG, *Early Alert* (August 2017) (<https://oig.hhs.gov/oas/reports/region1/11700504.pdf>).

penalties on nursing homes that repeatedly and/or seriously harm patients.⁹⁶ And in June, the Trump Administration put out a proposed rule that would allow nursing homes to force patients into arbitration to resolve disputes - allowing Medicaid-funded nursing homes to require patients to give up their legal rights to address poor care.⁹⁷

1. Will you commit to strong enforcement of CMS nursing home regulations?
2. Will you commit to aggressive use of civil monetary penalties in cases where nursing homes have caused repeat and/or serious harm to patients due to deficiencies in care?
3. What actions will you take to ensure that nursing home residents and their families are not stripped of their legal right to take a nursing home to court if they have suffered abuse or injury as a result of deficiencies in care?
4. What other actions will you take to address nursing home quality of care problems identified by the HHS Inspector General, by GAO, and by other experts

Please do not hesitate to reach out to Beth Pearson of my staff at 202-224-4543 with any questions or concerns. I look forward to reading your responses.

Best,



Elizabeth Warren
United States Senator

⁹⁶ CMS, Memo to State Survey Directors, 17-36-NH (June 30, 2017) (<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-36.pdf>); CMS, Memo to State Survey Directors, 18-01-NH (October 27, 2017) (<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-18-01.pdf>).

⁹⁷ 81 Fed. Reg 26649 (June 8, 2017).