

January 17, 2017

The Honorable Tom Price
Chairman
House Committee on the Budget
B-234 Longworth House Office Building
Washington, D.C. 20515

Dear Chairman Price,

On November 29, 2016, President-elect Donald Trump nominated you to serve as the Secretary of Health and Human Services ("HHS Secretary") in his Administration.¹ On January 18, 2017, you will appear before the U.S. Senate Committee on Health, Education, Labor, and Pensions ("HELP Committee") for a confirmation hearing that will precede a vote on your nomination.²

As a member of the HELP Committee, I am concerned about your ability to adequately fulfill the responsibilities of the HHS Secretary. The scheduled nomination hearing will offer only limited time for me to question you directly about your qualifications. Therefore, I am writing today to outline my concerns and request additional information to help me assess your suitability for the position. 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 full written answers to all questions promptly following the hearing.

The mission of the Department of Health and Human Services ("HHS") is 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."³ The agency conducts critical research at the National Institutes of Health ("NIH") and the Centers for Disease Control and Prevention ("CDC"). It regulates the safety of millions of foods, drugs,

¹ President-elect Donald J. Trump, "President-Elect Donald J. Trump Intends to Nominate Congressman Tom Price as Secretary of Health and Human Services and Seema Verma as Administrator of the Centers for Medicare and Medicaid Services," *GreatAgain.gov* (November 29, 2016) (online at <https://greatagain.gov/president-elect-trump-to-nominate-rep-price-as-hhs-secretary-seema-verma-as-cms-administrator-82b5c5439307#.g2d2yaes1>).

² U.S. Senate Committee on Health, Education, Labor, & Pensions, *Full Committee hearing: Nomination of Tom Price to serve as Secretary of Health and Human Services* (scheduled for Wednesday, January 18, 2017) (online at <http://www.help.senate.gov/hearings/nomination-of-tom-price-for->).

³ Department of Health and Human Services, "About HHS" (online at <https://www.hhs.gov/about/index.html#>).

medical devices, and other products at the Food and Drug Administration (“FDA”).⁴ It oversees Medicare, providing over 57 million seniors and people with disabilities with health care,⁵ and Medicaid, providing health care for over 73 million low-income adults, children, and people with disabilities.⁶ The agency also implements the Patient Protection and Affordable Care Act (“ACA”), which, since its passage in 2010, has increased the number of adults with health insurance by 20 million and has reduced the nation’s uninsured rate to a historic low.⁷

While there are many of us in Congress who would like to pursue improvements to the nation’s health care system, you have taken a less constructive, truly radical approach to health care policy. While serving in the House of Representatives, you championed legislation to repeal the ACA – a reckless step that could result in as many as 30 million Americans losing their health coverage, increase out-of-pocket costs for individuals with insurance, eliminate coverage for services such as maternity care, and reinstate annual and lifetime limits on benefits.⁸ You described the ACA’s ban on discriminating against individuals with pre-existing conditions as “a terrible idea.”⁹ You have consistently opposed improvements to women’s health care coverage: for example, you have voted ten times to defund Planned Parenthood, which provides lifesaving cancer and sexually transmitted infection screenings to millions of patients a year¹⁰ and have supported legislation that would eliminate the Title X Family Planning Program.¹¹ In addition, you are a co-sponsor of the *First Amendment Defense Act* (“FADA”), which would “effectively legalize” discrimination against LGBTQ individuals “among employers, businesses, landlords and healthcare providers,” jeopardizing the LGBTQ community’s access to health services.¹²

⁴ Department of Health and Human Services, “HHS Agencies & Offices” (online at <https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html>).

⁵ Centers for Medicare and Medicaid Services, “Medicare Enrollment Dashboard” (online at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/Dashboard.html>).

⁶ Kaiser Family Foundation, “Total Monthly Medicaid and CHIP Enrollment” (September 2016) (online at <http://kff.org/health-reform/state-indicator/total-monthly-medicaid-and-chip-enrollment/?currentTimeframe=0&selectedRows=%7B%22wrapups%22:%7B%22united-states%22:%7B%7D%7D%7D>).

⁷ Department of Health and Human Services, “ACA is working for Middle Class Families” (October 31, 2016) (online at <https://www.hhs.gov/healthcare/facts-and-features/fact-sheets/aca-working-middle-class-families/index.html>); Dan Mangan, “Obamacare pushes nation’s health uninsured rate to a record low 8.6 percent,” *CNBC* (September 7, 2016) (online at <http://www.cnn.com/2016/09/07/obamacare-pushes-nations-health-uninsured-rate-to-record-low.html>).

⁸ Congressman Tom Price, *H.R. 2300: Empowering Patients First Act—Section by Section Overview* (online at <http://tomprice.house.gov/sites/tomprice.house.gov/files/Section%20by%20Section%20of%20HR%202300%20Empowering%20Patients%20First%20Act%202015.pdf>).

⁹ Jennifer Haberkorn, “GOP Split on Reforming Health Care,” *Politico* (April 30, 2012) (online at: <http://www.politico.com/story/2012/04/gop-ers-split-over-how-to-reform-health-care-075767>).

¹⁰ Planned Parenthood, “Planned Parenthood at a Glance” (online at <https://www.plannedparenthood.org/about-us/who-we-are/planned-parenthood-at-a-glance>).

¹¹ See vote on H.R. 1 (February 19, 2011), the FY11 Continuing Resolution.

¹² Maggie Garrett, “Is Discrimination The Price We’ll Pay for Trump’s HHS Secretary?” *Americans United for Separation of Church and State* (November 11, 2016) (online at <https://www.au.org/blogs/wall-of-separation/is-discrimination-the-price-we-ll-pay-for-trump-s-hhs-secretary>); Jeff Taylor, “Donald Trump pledges to sign anti-LGBTQ ‘First Amendment Defense Act,’” *LGBTQ Nation* (September 26, 2016) (online at <http://www.lgbtqnation.com/2016/09/donald-trump-pledges-sign-anti-lgbtq-first-amendment-defense-act/>).

Furthermore, you have championed proposals that would privatize Medicare and increase the eligibility age for coverage.¹³ You have proposed radical restructuring of the Medicaid program through block-grant proposals that could leave millions of Americans uninsured, produce drastic cuts in benefits, and result in huge shifts in costs to states.¹⁴ These actions would weaken our nation's health care system and seriously undermine the ability of states to address public health crises such as the opioid epidemic and the Zika virus outbreak.

In addition to your stated policy positions, I am deeply concerned about the poor judgement that led you to actively trade in health-related stocks while pursuing legislation that would impact the value of those stocks. You have traded stock in a total of 40 pharmaceutical, biomedical, and healthcare companies since 2012. While serving in the 114th Congress, you traded stock in 12 such companies while co-sponsoring or sponsoring 44 health-related bills in the House and taking dozens of votes on health-related legislation.¹⁵ Your actions led to calls for Office of Congressional Ethics and Securities and Exchange Commission investigations into your finances to determine whether or not you violated the Stop Trading on Congressional Knowledge ("STOCK") Act or insider trading laws.¹⁶ I am deeply troubled at your actions and at the fact that your potential violations of the STOCK Act remain an open question. I do not believe your nomination should move forward before these questions are resolved.

The next HHS Secretary will inherit the immense responsibility of administering enrollment in the Affordable Care Act, managing the Medicare and Medicaid programs, enforcing consumer protections for health, food, drugs, and medical devices, addressing the nation's opioid epidemic, managing the FDA, NIH, and CDC, and responding to public health emergencies like the Ebola or Zika outbreaks of 2014 and 2016 – all amidst the massive market instability that will ensue if Republicans in Congress succeed in their goal to repeal the ACA without producing any replacement plan. After reviewing your record, I am not convinced that you are willing or able to handle these responsibilities. I am also not convinced that your policies and views as HHS Secretary would benefit the Commonwealth of Massachusetts, which has made critical strides as a result of Secretary Burwell's commitment to halting the nation's opioid epidemic.

The remainder of this letter provides details on my concerns and contains questions on these important subjects. To help me better understand how you would approach the position of HHS Secretary, please provide me with answers to the following questions promptly following your hearing.

¹³ U.S. House of Representatives Committee on the Budget, Chairman Tom Price, "A Balanced Budget for a Stronger America" (March 2016) (online at: http://budget.house.gov/uploadedfiles/fy2017_a_balanced_budget_for_a_stronger_america.pdf).

¹⁴ H.R. 2300; U.S. House of Representatives Committee on the Budget, Chairman Tom Price, "A Balanced Budget for a Stronger America" (March 2016) (online at: http://budget.house.gov/uploadedfiles/fy2017_a_balanced_budget_for_a_stronger_america.pdf).

¹⁵ James V. Grimaldi and Michelle Hackman, "Donald Trump's Pick for Health Secretary Traded Medical Stocks While in House," *Wall Street Journal* (December 22, 2016) (online at <http://www.wsj.com/articles/donald-trumps-pick-for-health-secretary-traded-medical-stocks-while-in-house-1482451061>).

¹⁶ Mary Ellen McIntire, "Democrats Call for Ethics Investigation Into Health Nominee's Stock Trades," *Morning Consult* (January 5, 2017) (online at <https://morningconsult.com/2017/01/05/dems-call-ethics-investigation-health-nominees-stock-trades/>).

CONFLICTS OF INTEREST

Congress passed the Stop Trading on Congressional Knowledge Act in March 2012 to prevent members of Congress from engaging in abusive insider trading practices.¹⁷ The act prohibits members of Congress and their staff from using “nonpublic information derived from the individual’s position ... or gained from performance of the individual’s duties for personal benefit.”¹⁸

But the *Wall Street Journal* reported last month that you have traded \$300,000 worth of stock in dozens of pharmaceutical, healthcare, and biomedical companies—including Pfizer, Aetna, and Amgen—since 2012.¹⁹ You made these trades while actively sponsoring, cosponsoring, or voting on dozens of bills that could affect these companies. Your perplexing decision to actively trade in health stocks while writing policy that could affect them raises serious questions about potential conflicts of interest and about your judgment.

According to your spokesman, you have “complied fully with all applicable laws and ethics rules governing [your] personal finances” while serving in the U.S. House of Representatives.²⁰

1. As Chairman of the House Budget Committee and as a key architect of health care legislation in the House, did you have access to “nonpublic information” about the health care industry during your time in Congress? If so, what safeguards did you put in place to ensure that when you made extensive health-care-industry-related financial trades, you did so without taking advantage of “nonpublic information derived from [your] position” as a Member of Congress?
2. Both Republican and Democratic ethics experts have advised Members of Congress to avoid even the appearance of conflicts of interest by placing their assets in investment vehicles like mutual funds.²¹ Why did you choose to continue trading in specific stocks and risk even the appearance of conflicts of interest?
3. The HHS Secretary is required to divest of any stock he or she owns in companies regulated by the Department of Health and Human Services, or recuse him or herself from any matter that relates to them.²² Why did you not take similar steps with regard to your investing behavior while in Congress?

¹⁷ James V. Grimaldi and Michelle Hackman, “Donald Trump’s Pick for Health Secretary Traded Medical Stocks While in House,” *Wall Street Journal* (December 22, 2016) (online at <http://www.wsj.com/articles/donald-trumps-pick-for-health-secretary-traded-medical-stocks-while-in-house-1482451061>).

¹⁸ Public Law 112-105 (online at <https://www.congress.gov/112/plaws/publ105/PLAW-112publ105.pdf>).

¹⁹ James V. Grimaldi and Michelle Hackman, “Donald Trump’s Pick for Health Secretary Traded Medical Stocks While in House,” *Wall Street Journal* (December 22, 2016) (online at <http://www.wsj.com/articles/donald-trumps-pick-for-health-secretary-traded-medical-stocks-while-in-house-1482451061>).

²⁰ Ibid.

²¹ Ibid.

²² Ibid.

REPEAL OF THE AFFORDABLE CARE ACT

Many members of Congress have ideas about how to improve the nation's health care system to lower costs for Americans and expand access to quality health care. But simply ripping up the ACA without a replacement plan is foolhardy, reckless, and destructive. Nonetheless, President-elect Trump and Senate and House Republicans have announced their intention to repeal the ACA during the opening weeks of the 115th Congress, using a budget reconciliation process²³ modeled after a similar budget reconciliation bill (H.R. 3762) that you introduced—and President Obama vetoed—last Congress.²⁴ They began this process by passing a budget resolution in the Senate during the early morning hours of January 12th.²⁵ It appears that these attempts to repeal the ACA through budget reconciliation could eliminate the law's Medicaid expansion; its premium tax credits and cost-sharing assistance for middle-income consumers; and many other provisions that encourage enrollment in health coverage and ensure that health care coverage meets citizens' needs.

In spite of the six-plus years you and your colleagues in the House and Senate have spent criticizing the ACA, Republicans have failed to reach a consensus on a replacement plan.²⁶ Key Republicans have proposed a delayed effective date for their repeal bill. As a result, if this repeal proposal proceeds, the ACA will remain in effect – perhaps for several years – while insurers, health care providers, and millions of Americans face grave uncertainty over the future of the health insurance market.

These foolhardy actions by Republican lawmakers will devastate the U.S. health care system. Analyses suggest that, should this repeal plan become law in 2017, the number of Americans without insurance will increase by as many as 30 million, leaving 59 million Americans uninsured in 2019.²⁷ According to experts, a repeal bill without a simultaneous replacement would “destabilize the individual market and very possibly cause it to collapse in some regions of the country during the interim period before any replacement is designed.”²⁸

²³ David Weigel, “Claiming mandate, GOP Congress lays plans to propel sweeping conservative agenda,” *Washington Post* (January 1, 2017) (online at https://www.washingtonpost.com/politics/claiming-mandate-gop-congress-lays-plans-to-propel-sweeping-conservative-agenda/2017/01/01/9840338a-ceee-11e6-b8a2-8c2a61b0436f_story.html?utm_term=.fff763e2decf).

²⁴ See H.R. 3762 (introduced October 16, 2015) (online at <https://www.congress.gov/bill/114th-congress/house-bill/3762>).

²⁵ S.Con.Res.3, FY 2017 Budget Resolution

²⁶ Alice M. Rivlin, Loren Adler, and Stuart M. Butler, “Why repealing the ACA before replacing it won’t work, and what might,” *Brookings Institute* (December 13, 2016) (online at <https://www.brookings.edu/research/why-repealing-the-aca-before-replacing-it-wont-work-and-what-might/>).

²⁷ Linda J. Blumberg, Matthew Buettgens, and Jon Holahan, “Implications of Partial Repeal of the ACA through Reconciliation,” *Urban Institute* (December 2016) (online at http://www.urban.org/sites/default/files/publication/86236/2001013-the-implications-of-partial-repeal-of-the-aca-through-reconciliation_0.pdf).

²⁸ Ibid.; Alice M. Rivlin, Loren Adler, and Stuart M. Butler, “Why repealing the ACA before replacing it won’t work, and what might,” *Brookings Institute* (December 13, 2016) (online at <https://www.brookings.edu/research/why-repealing-the-aca-before-replacing-it-wont-work-and-what-might/>).

Over 80% of the newly uninsured will come from working families.²⁹ As the number of uninsured increases dramatically, so too will the demand for uncompensated care: repealing the ACA without a replacement is expected to increase the cost of uncompensated care to \$145 billion over the next two years and to \$1.7 trillion over the next ten years.³⁰ It will also raise taxes on 7 million low- and moderate-income families, while providing millionaires with an average tax cut of almost \$60,000 by 2025.³¹

I am particularly concerned about the significant impacts that repeal of the ACA could have on families, insurers, and health providers in Massachusetts. Massachusetts was a leader in health care reform. We set up a health insurance exchange to make sure plans were affordable. We expanded Medicaid. And we have embarked on an ambitious Medicaid waiver that builds on the health care foundation provided by the ACA to improve care and lower costs for Medicaid beneficiaries. Today, more people in our state have health insurance than ever before – over 97% of Bay Staters are covered, the highest rate of any state in the country.³² Repeal of the ACA would dramatically undermine our efforts to provide high-quality, affordable health insurance to all our residents.³³

I am further troubled by the fact that – aside from your threats to repeal the law —you have repeatedly championed health care bills that would gut the consumer protections contained in the ACA. The ACA requires insurers to fully cover preventive care with no cost-sharing and include a set of essential health benefits in all qualified health plans.³⁴ Plans cannot contain annual or lifetime limits.³⁵ They cannot charge women more than men for coverage,³⁶ and they

²⁹ Linda J. Blumberg, Matthew Buettgens, and Jon Holahan, “Implications of Partial Repeal of the ACA through Reconciliation,” *Urban Institute* (December 2016) (online at http://www.urban.org/sites/default/files/publication/86236/2001013-the-implications-of-partial-repeal-of-the-aca-through-reconciliation_0.pdf).

³⁰ Linda J. Blumberg, Matthew Buettgens, and Jon Holahan, “Implications of Partial Repeal of the ACA through Reconciliation,” *Urban Institute* (December 2016) (online at http://www.urban.org/sites/default/files/publication/86236/2001013-the-implications-of-partial-repeal-of-the-aca-through-reconciliation_0.pdf).

³¹ Chye-Ching Huang and Paul Van de Water, “Millionaires the Big Winners From Repealing the Affordable Care Act, New Data Show,” *Center on Budget and Policy Priorities* (December 15, 2016) (online at <http://www.cbpp.org/research/federal-tax/millionaires-the-big-winners-from-repealing-the-affordable-care-act-new-data>).

³² Jessica C. Barnett and Marina S. Vornovitsky, U.S. Census Bureau, “Health insurance coverage in the United States: 2015” (Sept. 2016) (<http://www.census.gov/content/dam/Census/library/publications/2016/demo/p60-257.pdf>). Accessed Jan. 5, 2017.

³³ Linda J. Blumberg, Matthew Buettgens, and Jon Holahan, “Implications of Partial Repeal of the ACA through Reconciliation,” *Urban Institute* (December 2016) (online at http://www.urban.org/sites/default/files/publication/86236/2001013-the-implications-of-partial-repeal-of-the-aca-through-reconciliation_0.pdf).

³⁴ See the H.R. 3590: Patient Protection and Affordable Care Act, Sections 2713, 2707, 1301, and 1302 (online at <http://housedocs.house.gov/energycommerce/ppacacon.pdf>).

³⁵ See the H.R. 3590: Patient Protection and Affordable Care Act, Section 2711 (online at <http://housedocs.house.gov/energycommerce/ppacacon.pdf>).

³⁶ See the H.R. 3590: Patient Protection and Affordable Care Act, Sections 2701 and 2706 (online at <http://housedocs.house.gov/energycommerce/ppacacon.pdf>).

must abide by strict limits on how cost of coverage may vary by age.³⁷ Insurers may not refuse coverage or require that consumers pay more for coverage due to a pre-existing condition.³⁸

During a recent “Weekly Republican Address,” you promised to implement health policies that provide Americans with “real protections so you never have to worry about being turned away because of your age or your income or your health status.”³⁹ However, your *Empowering Patients First* bill would allow insurers to charge higher premiums to women and people with certain health conditions. It would enable insurers to offer plans that do not include maternity care or prescription drugs, permit them to reinstate annual and lifetime limits on benefits, and allow them to limit coverage of pre-existing conditions.⁴⁰

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 if the health care market enters the “death spiral” that analysts predict will occur following a partial repeal of the ACA through budget reconciliation?⁴¹
2. Will you guarantee that, if Congress repeals the ACA, you will take all necessary steps to ensure that no American loses health insurance or pays higher premiums as a result of the ACA repeal?
3. Will you ensure that, if Congress repeals the ACA, individuals who qualify for coverage through the Medicaid expansion continue to receive coverage until a replacement plan is in effect?
4. If confirmed as HHS Secretary, you will be responsible for enforcing the insurance protections instituted in the ACA.
 - a. Will you commit to vigorously enforcing these protections in your new role?
 - b. Specifically, please describe the steps you would take to improve enforcement and oversight to ensure that Americans continue to have access to the following ACA consumer protections.

³⁷ See the H.R. 3590: Patient Protection and Affordable Care Act, Section 2701 (online at <http://housedocs.house.gov/energycommerce/ppacacon.pdf>).

³⁸ See the H.R. 3590: Patient Protection and Affordable Care Act, Section 2704 and 2705 (online at <http://housedocs.house.gov/energycommerce/ppacacon.pdf>).

³⁹ Congressman Tom Price, “Weekly Republican Address: A Better Way to Fix Health Care” (September 30, 2016) (online at <http://www.speaker.gov/press-release/weekly-republican-address-better-way-fix-health-care>).

⁴⁰ Congressman Tom Price, *H.R. 2300: Empowering Patients First Act—Section by Section Overview* (online at <http://tomprice.house.gov/sites/tomprice.house.gov/files/Section%20by%20Section%20of%20HR%202300%20Empowering%20Patients%20First%20Act%202015.pdf>).

⁴¹ Larry Levitt, “Repeal of Obamacare could cause the ‘death spiral’ critics warned about,” *Los Angeles Times* (December 12, 2014) (online at <http://www.latimes.com/opinion/op-ed/la-oe-levitt-death-spiral-20161212-story.html>).

- i. Provisions that prevent insurers from refusing coverage to patients with pre-existing conditions;
 - ii. Provisions that prevent insurers from charging exorbitant out of pocket costs;
 - iii. Provisions that prevent insurers from charging women more for coverage than men;
 - iv. Provisions that prohibit insurers from establishing annual or lifetime limits on coverage;
 - v. Provisions that prohibit insurers from rescinding coverage for the seriously ill;
 - vi. Provisions that require certain insurers to provide preventive health care with no cost-sharing;
 - vii. Provisions that guarantee insurance renewal for patients who pay their premiums in full; and
 - viii. Provisions that expand insurance coverage of mental health and substance use disorder services.
- c. Will you commit that you will not seek to unravel or delay any of these protections through the rulemaking process or by issuing new agency guidance? Please provide answers with respect to the specific protections listed below:
- i. Provisions that prevent insurers from refusing coverage to patients with pre-existing conditions;
 - ii. Provisions that prevent insurers from charging exorbitant out of pocket costs;
 - iii. Provisions that prevent insurers from charging women more for coverage than men;
 - iv. Provisions that prohibit insurers from establishing annual or lifetime limits on coverage;
 - v. Provisions that prohibit insurers from rescinding coverage for the seriously ill;
 - vi. Provisions that require certain insurers to provide preventive health care with no cost-sharing;

- vii. Provisions that guarantee insurance renewal for patients who pay their premiums in full; and
- viii. Provisions that expand insurance coverage of mental health and substance use disorder services.

MEDICARE AND MEDICAID

Your dangerous proposal to abolish the Affordable Care Act has been called “the least controversial part of [your] health care agenda” because it pales in comparison to the changes to the Medicare and Medicaid programs that you have supported.⁴² These programs provide health coverage to more than one hundred million people—about one in three Americans. But you have stated that you and your Republican colleagues “will not rest until we make certain that government-run health care is ended.”⁴³

Your Medicaid plan would begin with “repealing the expansion”⁴⁴ under the Affordable Care Act that has provided coverage to over 11 million Americans.⁴⁵ Your bill to take away this health insurance coverage does not contain a plan to ensure that these low-income Americans receive replacement coverage. Instead, you propose offering low-income Americans a tax credit and a health savings account.⁴⁶

You have proposed replacing Medicaid—which currently reimburses states for a majority of their costs of providing health services to low-income families and individuals—with lump-sum payments. This would “institute deep cuts to federal funding” and “threaten benefits for tens of millions of low-income families, senior citizens, and people with disabilities.”⁴⁷ 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.”⁴⁸ This would jeopardize

⁴² Adam Cancryn, Jennifer Haberkorn, and Rachana Pradhan, “Tom Price’s Radically Conservative Vision for American Health Care,” *Politico* (November 29, 2016) (online at: <http://www.politico.com/story/2016/11/tom-price-radically-conservative-healthcare-vision-231965>).

⁴³ Nancy Altman, “Donald Trump’s New ‘Health’ Secretary Wants to Destroy Medicare,” *Huffington Post* (November 29, 2016) (online at http://www.huffingtonpost.com/nancy-altman/donald-trumps-new-health_b_13307316.html).

⁴⁴ U.S. House of Representatives Committee on the Budget, Chairman Tom Price, “A Balanced Budget for a Stronger America: Fiscal Year 2017 Budget Resolution” (March 2016) (online at: http://budget.house.gov/uploadedfiles/fy2017_a_balanced_budget_for_a_stronger_america.pdf), p. 29.

⁴⁵ Department of Health and Human Services, “Medicaid Enrollment and the Affordable Care Act” (March 20, 2015) (online at https://aspe.hhs.gov/sites/default/files/pdf/139236/ib_MedicaidEnrollment.pdf).

⁴⁶ Congressman Tom Price, *H.R. 2300: Empowering Patients First Act—Section by Section Overview* (online at <http://tomprice.house.gov/sites/tomprice.house.gov/files/Section%20by%20Section%20of%20HR%202300%20Empowering%20Patients%20First%20Act%202015.pdf>).

⁴⁷ 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: <http://www.cbpp.org/research/health/medicaid-block-grant-would-slash-federal-funding-shift-costs-to-states-and-leave>).

⁴⁸ 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:

care for millions of patients—including the 1.3 million nursing home residents who live in facilities that are primarily funded by Medicaid.⁴⁹

You have also proposed to end Medicare as we know it, replacing the program’s traditional, guaranteed benefit with a private voucher program that would leave seniors on their own to purchase insurance and raise the eligibility age to 67.⁵⁰ The Congressional Budget Office (“CBO”) estimates that raising the Medicare eligibility age to 67 would increase the number of uninsured by 300,000 people by 2026.⁵¹ Privatizing Medicare would raise out-of-pocket costs for beneficiaries and severely weaken the traditional Medicare system; according to CBO, voucherizing Medicare could increase out-of-pocket costs by 11%.⁵²

Your views on Medicare and Medicaid stand in sharp contrast to the promises of the President-elect, who has asserted that “I’m not going to cut Medicare or Medicaid.”⁵³ If confirmed as HHS Secretary, you will be responsible for managing Medicare and Medicaid – programs that you have consistently sought to weaken, cut, and privatize.

1. How will you reconcile your goals of privatizing and cutting Medicare and Medicaid with the President-elect’s commitment to preserving these programs?
2. Privatizing Medicare through a voucher system will transfer costs from the federal government to seniors, forcing them to pay more in out-of-pocket costs.⁵⁴ The vast majority of Medicare benefits are mandated by law and cannot be changed administratively. But 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. 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 increase out-of-pocket costs for seniors or move towards privatizing Medicare?

<http://www.cbpp.org/research/health/medicaid-block-grant-would-slash-federal-funding-shift-costs-to-states-and-leave>).

⁴⁹ Charlene Harrington, Helen Carrillo, Kaiser Family Foundation, “Nursing facilities, staffing, residents, and facility deficiencies, 2009-2014” (August 2015) (<http://ltcombudsman.org/uploads/files/library/deficiencies-09-14.pdf>).

⁵⁰ David Lawder, “Paul Ryan’s Bid to Overhaul Medicare to Resurface in New Congress,” *Reuters* (December 12, 2014) (online at: <http://www.reuters.com/article/usa-congress-budget-price-idUSL1N0TW1KQ20141212>); “HHS nominee Price opposes Obamacare, backs Medicare vouchers,” *U.S. News & World Report* (November 29, 2016) (online at <http://www.usnews.com/news/politics/articles/2016-11-29/hhs-nominee-price-opposes-obamacare-backs-medicare-vouchers>).

⁵¹ Congressional Budget Office, “Options for Reducing the Deficit: 2017 to 2026” (December 2016) (online at: <https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/reports/52142-budgetoptions2.pdf>).

⁵² Congressional Budget Office, “A Premium Support System for Medicare: Analysis of Illustrative Options” (September 2013) (online at <http://www.cbo.gov/sites/default/files/cbofiles/attachments/09-18-PremiumSupport.pdf>).

⁵³ Donald J. Trump for President, “Why Donald Trump Won’t Touch your Entitlements” (May 21, 2015) (<https://www.donaldjtrump.com/media/why-donald-trump-wont-touch-your-entitlements>).

⁵⁴ Congressional Budget Office, “A Premium Support System for Medicare: Analysis of Illustrative Options” (September 2013) (online at <http://www.cbo.gov/sites/default/files/cbofiles/attachments/09-18-PremiumSupport.pdf>).

3. 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.⁵⁵ Experts agree that your plan to replace Medicaid with lump-sum, no-strings-attached block grants to the states would reduce state budgets by \$1 trillion over ten years, severely limiting states' ability to provide care to low-income populations. Can you reassure Americans that, as HHS Secretary, you will not use your administrative authority 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?
4. In the Medicare Part B program, spending on prescription drugs increased by an average annual rate of 7.7 percent between 2005 and 2014, with just 20 drugs accounting for 57 percent of the costs.⁵⁶ In March 2016, CMMI proposed a Medicare Part B drug payment demonstration that aimed to transition Medicare from a volume-based system to one that reimburses based on health care quality and innovation.⁵⁷ You have opposed the Part B demonstration. In November 2016, CMS stated that it would not be finalizing rulemaking for the Demonstration during the Obama Administration.⁵⁸
 - a. Are you committed to continuing to test innovative solutions to lower drug prices for Medicare Part B, as well as other aspects of the Medicare program?
 - b. What specific efforts will you pursue to ensure that the Medicare Part B drug payment program ensures access to necessary medications, builds on existing payment reform models, enhances private sector payment innovations, and promotes value?
 - c. Do you agree with President-elect Trump's support for allowing the government to negotiate for lower Medicare drug prices?
5. I am a strong supporter of the use of unique device identifiers ("UDIs") for medical devices and their inclusion in Medicare claims. The use of these device identifiers would

⁵⁵ Kaiser Family Foundation, "Medicaid Pocket Primer" (January 3, 2017) (online at <http://kff.org/medicaid/fact-sheet/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>).

⁵⁶ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, "Issue Brief: Medicare Part B drugs: Pricing and incentives" (March 8, 2016) (online at <https://aspe.hhs.gov/sites/default/files/pdf/187581/PartBDrug.pdf>).

⁵⁷ 81 FR 13229, "Medicare program; Part B drug payment model" (March 11, 2016) (online at <https://www.federalregister.gov/articles/2016/03/11/2016-05459/medicare-program-part-b-drug-payment-model>).

⁵⁸ Zachary Brennan, *Regulatory Affairs Professional Society*, "CMS drops Medicare Part B drug payment pilot" (Dec. 16, 2016) (online at <http://raps.org/Regulatory-Focus/News/2016/12/16/26388/CMS-Drops-Medicare-Part-B-Drug-Payment-Pilot/>).

improve safety (allowing regulators to identify and recall faulty or dangerous devices more rapidly) and cut costs for Medicare.⁵⁹

- a. The American Academy of Orthopedic Surgeons (“AAOS”), of which you are a member,⁶⁰ has stated that UDIs “will significantly enhance post-market surveillance activities” by providing a standard and unambiguous way to document device use in electronic health records, clinical information systems, claims data sources, and registries.”⁶¹ As an orthopedic surgeon, do you agree with the AAOS that including device identifier information would be beneficial for patients and for the medical system?
 - b. If confirmed Secretary, will you continue to advance the process of adding device identifiers to claims?
6. In 2014, approximately 1.35 million residents lived in over 15,400 nursing homes across the country. This care is enormously expensive, costing upwards of \$40,000 per year. Medicare and Medicaid pay for the vast majority of this care, providing the foundation for safe, high-quality and affordable skilled nursing facility (“SNF”) care for seniors and disabled people, and protecting many middle class families from the burden of these high costs.⁶² The HHS Secretary is responsible for ensuring that the nation’s most vulnerable populations have access to safe, high-quality care in these facilities.
- a. If confirmed Secretary, will you commit to ensuring that Medicare and Medicaid continue to provide federal support to SNFs so that members of our elderly and disabled communities are well taken care of? What specific steps will you take to protect the families whose loved ones reside in SNFs from financial hardship?
 - b. The Centers for Medicare and Medicaid Services recently issued a final rule updating requirements for SNFs to receive federal support, which included a prohibition on the use of forced arbitration clauses as a requirement for admission.⁶³ This rule was recently challenged in court by the American Health

⁵⁹ Department of Health and Human Services Office of Inspector General, *Early Alert: Incorporating Medical Device-Specific Information on Claim Forms* (September 30, 2016) (online at <https://oig.hhs.gov/oas/reports/region1/11600510.pdf>).

⁶⁰ American Academy of Orthopedic Surgeons, “AAOS Statement on Nomination of Orthopedic Surgeon Tom Price” (November 29, 2016) (online at <http://newsroom.aaos.org/media-resources/Press-releases/aaos-statement-on-nomination-of-orthopaedic-surgeon-tom-price.htm>).

⁶¹ American Academy of Orthopedic Surgeons letter to Acting FDA Commissioner Stephen Ostroff (Oct. 26, 2015) (online at http://www.aaos.org/uploadedFiles/PreProduction/Advocacy/Federal/FDA/AAOS_FDA%20Comment%20Letter%20on%20MDEpiNet%20Report_FINAL%20%20.pdf).

⁶² Charlene Harrington, Helen Carrillo, Kaiser Family Foundation, “Nursing facilities, staffing, residents, and facility deficiencies, 2009-2014” (August 2015) (online at <http://ltombudsman.org/uploads/files/library/deficiencies-09-14.pdf>).

⁶³ 81 FR 68688 (Oct. 4, 2016) (online at <https://www.federalregister.gov/documents/2016/10/04/2016-23503/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities>). *Note:* This rule was recently challenged by the American Health Care Association. On Nov. 7, 2016, the U.S. District Court for the Northern District of Mississippi granted a preliminary injunction. (The rule was supposed to be effective Nov. 28,

Care Association. Would you recommend to the Department of Justice that the administration defend this aspect of the rule? Will you commit to implementing the remainder of this rule as written, without delay?

- c. Will you take any action to reduce the frequency of required nursing home inspections or penalties for nursing homes that fail to meet required standards?

HEALTH CARE FOR WOMEN

Throughout your time in the House of Representatives, you exhibited an indifference to women's health care needs. Your legislative record is littered with attempts to limit women's access to legal abortion and reduce funding for sexually transmitted infection ("STI" testing and contraceptive services. As HHS Secretary, however, you would be responsible for "enhance[ing] and protect[ing] the health and well-being of all Americans"—including women. This would require administering a variety of programs, including reproductive health services. If you are unable or unwilling to administer these programs, you are not qualified to be the HHS Secretary.

1. Prior to the full implementation of the ACA, one in five women reported that they "put off or postponed preventive services" due to cost.⁶⁴ 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"). Under current law, women are entitled to free STI & HIV counseling and screening, contraception, breast and cervical cancer screenings, and breastfeeding counseling, among other services. On December 20, 2016, HRSA updated its list of recommended preventive services for women to include mammography coverage.
 - a. As Secretary of HHS, would you continue to define "preventive services" for women to include contraception and STI counseling and screening?
 - b. As Secretary of HHS, would you continue to define "preventive services" for women to include breast cancer, cervical cancer, and colorectal cancer counseling and screening?
 - c. As Secretary of HHS, would you continue to define "preventive services" to include breastfeeding counseling, consultations, and equipment rental?

2016) (November 8, 2016) (online at <http://khn.org/morning-breakout/federal-judge-blocks-administrations-new-rule-that-allows-residents-to-sue-nursing-homes/>).

⁶⁴ 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>).

- d. If you answered “no” to any of the above questions, how would you ensure that women have access to affordable preventive care services?
 - e. If HRSA adds any additional recommendations for preventive services, will you commit to add these services to the list of "essential health benefits"?
2. The Title X Family Planning Program, established in 1970 with bipartisan support, funds basic reproductive health services—including cancer screenings, STI testing, and birth control—to over 4 million low-income Americans. HHS administers the Title X program through the Office of Population Affairs (“OPA”) and HRSA.⁶⁵ In spite of the critical services provided by Title X, you and your Republican colleagues have consistently voted to defund the program and limit the types of clinics that can receive Title X funds.⁶⁶ To preserve access to care for millions of low-income Americans, HHS finalized its rulemaking on *Compliance With Title X Requirements by Project Recipients in Selecting Subrecipients* in December 2016. The rule clarifies that Title X recipients cannot be barred from receiving funds “on bases unrelated to their ability to provide Title X services effectively.” The rule goes into effect on January 18, 2017.⁶⁷
 - a. Will you commit, as HHS Secretary, to implement this new rule without change and without delay to ensure that low-income Americans can access cancer screenings, STI testing, and birth control through Title X?
 - b. As HHS Secretary, would you commit to the goal of improving access to cancer screenings, STI testing, and birth control?
 3. Section 2038 of the 21st Century Cures Act (Public Law 114-255) requires the National Institutes of Health (NIH) to “improve research related to minority populations,” “update guidelines for the inclusion of women in clinical research,” and gather data on the inclusion of women and minorities in the study populations of federally-funded clinical research.⁶⁸
 - a. Please provide a set of specific steps that HHS would take under your leadership to support NIH’s requirement to update guidelines for the inclusion of women in clinical research.

⁶⁵ National Family Planning & Reproductive Health Association, “Title X: An Introduction to the Nation’s Family Planning Program” (February 2016) (online at <http://www.nationalfamilyplanning.org/file/documents---fact-sheets/Title-X-101-Updated.pdf>).

⁶⁶ See, for example, H.R. 1 (February 19, 2011) (online at <http://projects.washingtonpost.com/congress/112/house/1/votes/147/>).

⁶⁷ 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>).

⁶⁸ House Energy and Commerce Committee, “The 21st Century Cures Act (2016): Section-by-Section Summary” (online at <https://energycommerce.house.gov/cures>).

- b. Please provide a set of specific steps that HHS would take under your leadership to meet NIH's requirements to improve research related to minority populations.
- c. Please provide a set of specific steps that HHS would take under your leadership to support NIH's requirements to gather data on the inclusion of women and minorities in the study populations of federally-funded clinical research.

HEALTH CARE FOR THE LGBTQ COMMUNITY

While serving in the House of Representatives, you have also exhibited a disdain for the LGBTQ community. In addition to your efforts to ban same-sex marriage, you are a co-sponsor of the *First Amendment Defense Act*, which, if passed, would permit health care providers to discriminate against patients that identify as LGBTQ.⁶⁹ Again, as HHS Secretary, you would be responsible for “enhance[ing] and protect[ing] the health and well-being of all Americans”—including the LGBTQ community. If you are unable or unwilling to protect the health of LGBTQ Americans, you should withdraw your name from consideration as HHS Secretary.

1. You are a co-sponsor of the *First Amendment Defense Act*, which would permit health care providers to discriminate against patients that identify as LGBTQ.⁷⁰
 - a. Do you believe that health care providers should be allowed to refuse care to an LGBTQ-identified individual?
 - b. What steps would you take as HHS Secretary to ensure that LGBTQ-individuals have the same access to health care as non-LGBTQ-identified individuals?
2. Ensuring a safe and adequate blood supply is a critical aspect of our public health system. The FDA develops blood donation policy for the nation's blood banks – a task that is even more important as we respond to emerging diseases such as the Zika virus that threaten the safety of our blood supply. Ensuring that blood donation policies are founded in science and that the FDA utilizes risk-based deferral criteria is a key aspect of ensuring the safety and reliability of our blood supply.
 - a. As Secretary of HHS, how would you support the FDA's efforts to move to a risk-based referral policy for all blood donors?
 - b. What other steps will you take as HHS Secretary to ensure that our nation has a steady, safe supply of blood for patients who need it?

⁶⁹ Jeff Taylor, “Donald Trump pledges to sign anti-LGBTQ ‘First Amendment Defense Act,’” *LGBTQ Nation* (September 26, 2016) (online at <http://www.lgbtqnation.com/2016/09/donald-trump-pledges-sign-anti-lgbtq-first-amendment-defense-act/>); See H.R. 2802—First Amendment Defense Act (online at <https://www.congress.gov/bill/114th-congress/house-bill/2802/cosponsors>).

⁷⁰ Jeff Taylor, “Donald Trump pledges to sign anti-LGBTQ ‘First Amendment Defense Act,’” *LGBTQ Nation* (September 26, 2016) (online at <http://www.lgbtqnation.com/2016/09/donald-trump-pledges-sign-anti-lgbtq-first-amendment-defense-act/>); See H.R. 2802—First Amendment Defense Act (online at <https://www.congress.gov/bill/114th-congress/house-bill/2802/cosponsors>).

THE IMPORTANCE OF SCIENCE IN HEALTH POLICY

In one of your first speeches on the floor of the House of Representatives, you vehemently advocated for the importance of science in policymaking. “[A]s a physician,” you stated, “I’m certain of one thing: Science is not Republican or Democrat, science is not conservative or liberal. Science is science. Decisions in science should be based on the scientific method—a standardized method of evaluation and implementation of a solution or treatment of a disease.”⁷¹ Your commitment to science is important, given the essential role of scientific, evidence-based policies at the Department of Health and Human Services.

However, you are also a member of the Association of American Physicians and Surgeons (“AAPS”), a “fringe” medical association that promotes pseudoscientific, inaccurate conspiracy theories. AAPS, for asserts that physicians who participate in Medicare and Medicaid as “immoral” and “evil”;⁷² describes electronic medical records as “Big Brother medical databases,”⁷³ and portrays enhancements in electronic medical records as a form of “data control.”⁷⁴

1. According to AAPS, tax hikes on tobacco products are harmful to public health.⁷⁵ The views of AAPS are consistent with those of Vice-President-elect Mike Pence, who stated in 2000 that “[d]espite the hysteria from the political class and the media, smoking doesn’t kill.”⁷⁶ Do you agree with AAPS that tax hikes on tobacco products are harmful to public health? Do you agree with Vice-President-elect Pence that smoking “doesn’t kill”?
2. AAPS promotes scientifically inaccurate claims about vaccinations. The organization opposes mandatory vaccinations as a requirement for entry in public schools, and has linked vaccinations to autism and shaken baby syndrome.⁷⁷ The views of AAPS are consistent with those of President-elect Trump, who has used his Twitter account to argue that “something must be done immediately” about the “big increase in autism” caused by vaccines.⁷⁸ Do you agree with President-elect Trump and AAPS that vaccinations are

⁷¹ <https://www.congress.gov/crec/2005/05/24/CREC-2005-05-24-pt1-PgH3809.pdf>

⁷² Stephanie Mencimer, “The Tea Party’s Favorite Doctors,” *Mother Jones* (November 18, 2009) (online at <http://www.motherjones.com/politics/2009/11/tea-party-doctors-american-association-physicians-surgeons>).

⁷³ Association of American Physicians and Surgeons, “President’s Page: What Is Our Mission?” (October 12, 2016) (online at <http://aapsonline.org/presidents-page-what-is-our-mission/>).

⁷⁴ Jane M. Orient, M.D., Executive Director of the Association of American Physicians and Surgeons, “Statement of the Association of the Association of American Physicians and Surgeons on Computer-Based Patient Records” (December 8, 1998) (online at <http://www.aapsonline.org/confiden/ncvhs.htm>).

⁷⁵ Jesse Singal, “Tom Price Belongs to a Really Scary Medical Organization That Promotes Anti-Vaccine Hysteria,” *New York Magazine* (December 1, 2016) (online at <http://nymag.com/scienceofus/2016/12/tom-price-belongs-to-a-really-scary-medical-organization.html>).

⁷⁶ Erin Schumaker, “Remember When Mike Pence Said Smoking Doesn’t Kill?” *Huffington Post* (October 28, 2016) (online at http://www.huffingtonpost.com/entry/mike-pence-said-smoking-doesnt-kill_us_58121434e4b064e1b4b0bf93).

⁷⁷ “HHS nominee Tom Price and a radical right-wing physician organization,” *DailyKos* (November 30, 2016) (online at <http://www.dailykos.com/story/2016/11/30/1605701/-HHS-nominee-Tom-Price-and-a-radical-right-wing-physician-organization>).

⁷⁸ See the Twitter Feed of President-elect Donald Trump (@realDonaldTrump).

linked to autism or shaken baby syndrome, or do you agree with the scientific consensus that vaccines are safe and effective?⁷⁹

3. AAPS has described electronic medical records as “Big Brother medical databases” that are a form of “data control.”⁸⁰ Do you agree with this assessment?
4. AAPS has promoted the false claim that abortions increase the risk of breast cancer—a claim that the National Cancer Institute (“NCI”), the American Cancer Society (“ACS”), and the American College of Obstetricians and Gynecologists (“ACOG”) dispute.⁸¹ Do you agree with the NCI, the ACS, and the ACOG that abortions do not cause breast cancer?

HALTING THE OPIOID EPIDEMIC

The opioid epidemic is a public health crisis, and addressing it must be a top priority for Congress and the Administration. The federal government must do more to work with state and local governments, including public health officials, law enforcement, and community leaders to implement comprehensive strategies for prevention, treatment, and recovery and to reduce the stigma for Americans dealing with substance abuse disorder. HHS plays a critical role in this work and as Secretary you must be prepared to build on the work of the previous Administration, support Congressional and state efforts, and take an evidence-based, collaborative approach to public health policy.

1. The National Institute on Drug Abuse has estimated that over 70% of adults who misuse prescription opioids receive their drugs from friends and relative.⁸² The Comprehensive Addiction and Recovery Act, passed in July 2016, empowers patients to talk to their physicians and pharmacists about partially filling their prescription medications in order to reduce the amount of unused opioids available for misuse.⁸³
 - a. How will you work with states, physicians, pharmacists, and patient groups to increase awareness about partial fill policies?
 - b. What metrics will you use to measure success?
 - c. What other approaches do you think HHS can take to reduce the amount of unused prescription opioids in circulation?

⁷⁹ Centers for Disease Control and Prevention, “Vaccines Do Not Cause Autism” (online at <https://www.cdc.gov/vaccinesafety/concerns/autism.html>).

⁸⁰ Stephanie Mencimer, “The Tea Party’s Favorite Doctors,” *Mother Jones* (November 18, 2009) (online at <http://www.motherjones.com/politics/2009/11/tea-party-doctors-american-association-physicians-surgeons>).

⁸¹ *Ibid.*

⁸² National Institute on Drug Abuse, *Popping Pills: A Drug Buse Epidemic* (online at <https://www.drugabuse.gov/sites/default/files/poppingpills-nida.pdf>).

⁸³ See S. 524: Comprehensive Addiction and Recovery Act of 2016 (online at <https://www.congress.gov/bill/114th-congress/senate-bill/524/text>).

2. The overprescribing of prescription painkillers is a major driver of the opioid epidemic. CMS reported that generic Vicodin was prescribed to more Medicare beneficiaries than any other drug in 2013.⁸⁴ What will you do to work with other federal and state agencies and the physician community to halt this alarming trend?
3. Medical marijuana has the potential to mitigate the effects of the opioid crisis. A 2014 *JAMA Internal Medicine* study, for example, found that the fatal opioid overdose rate was 25% lower in states that allow for the use of medical marijuana than in states that do not.⁸⁵
 - a. As HHS Secretary, what would you do to further study this potential alternative?
 - b. Are you committed to implementing evidence-based policies regarding its use?
4. The increased illegal sale of fentanyl, a synthetic opioid, has also contributed to the opioid crisis – particularly in Massachusetts. A November 2016 study by the Massachusetts Department of Public Health found that 74% of individuals in opioid-related fatalities tested positive for fentanyl.⁸⁶
 - a. How will you address the illegal sale of fentanyl?
 - b. What other federal, state, and local agencies do you plan on working with to improve surveillance of fentanyl abuse?
 - c. How will you support the work of states dealing with high rates of opioid overdoses due to illicitly produced fentanyl?
5. As HHS Secretary, would you commit to proposing budgets that take full advantage of funding streams to combat the opioid epidemic authorized in the 21st Century Cures Act? What criteria will you use for distributing these funds among states?⁸⁷

⁸⁴ Centers for Medicare & Medicaid Services, “CMS releases prescriber-level Medicare data for first time” (April 30, 2016) (online at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-04-30.html>).

⁸⁵ Marcus A. Bachhuber, Brendan Saloner, Chinazo Cunningham et al., “Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States, 1999-2010,” *Journal of the American Medical Association* (October 2014) (online at <http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1898878>).

⁸⁶ 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>).

⁸⁷ H.R. 34, “21st Century Cures Act” (<https://www.congress.gov/bill/114th-congress/house-bill/34/text>). Accessed Jan. 8, 2017.

INCREASED FUNDING FOR BIOMEDICAL RESEARCH

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are critical to the next generation of biomedical innovation. These agencies need predictable, robust funding in order to conduct the research, development, and review of tomorrow's new discoveries and medical breakthroughs. The state of Massachusetts relies on NIH funding to continue to pioneer scientific innovations: in FY2015 alone, the 172 NIH-funded institutions in the state received a total of 4,914 NIH grants.⁸⁸

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. However, your record on sustained support for scientific research is inconsistent.⁸⁹ You have expressed your support for "provid[ing] much greater resources in the National Science Foundation and the NIH and the CDC and others that ultimately work and derive huge benefit to our entire society and, in fact, to the world,"⁹⁰ but you have also pushed overall federal spending cuts and opposed expanding the NIH budget.⁹¹

The 21st Century Cures Act provided funding to support several scientific initiatives launched by the Obama Administration: the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, the Precision Medicine Initiative (PMI), and the Beau Biden Cancer Moonshot. However, as former Deputy Director of Science, Outreach and Policy Kathy Hudson and Director Francis Collins of the NIH noted, "Congress has made it clear that these focused investments are not intended as a substitute or offset for providing NIH research through the regular appropriations process."⁹² The same is true for the additional funding provided to the FDA through the 21st Century Cures Act.

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

⁸⁸ Federation of American Societies for Experimental Biology, "Massachusetts: National Institutes of Health State Funding Facts for FY2015" (online at <http://www.faseb.org/viewer.aspx?id=209&nocache=636039102394518203&Name=Value-of-NIH-Funding-in-Massachusetts.pdf>).

⁸⁹ See, for example, Sara Reardon, *Nature*, "Trump's pick for US health secretary has pushed to cut science spending" (Nov. 29, 2016) (online at <http://www.nature.com/news/trump-s-pick-for-us-health-secretary-has-pushed-to-cut-science-spending-1.21066>).

⁹⁰ Congressional Record, 110th Congress, 1st Session, Issue: Vol. 153, No. 71 — Daily Edition (May 2, 2007) (<https://www.congress.gov/congressional-record/2007/5/2/house-section/article/h4380-1?q=%7B%22search%22%3A%5B%22NIH%22%5D%7D&r=7>). Accessed Jan. 8, 2017.

⁹¹ Office of the Clerk of the U.S. House of Representatives, Final vote results for roll call 433 (114th Congress, 2nd session) (July 10, 2015) (<http://clerk.house.gov/evs/2015/roll433.xml>); U.S. House of Representatives Committee on the Budget, "Price statement on 21st Century Cures Act" (July 10, 2015) (<http://budget.house.gov/news/documentsingle.aspx?DocumentID=393978>). Accessed Jan. 8, 2017.

⁹² Kathy L. Hudson and Francis S. Collins, "The 21st Century Cures Act — A View from the NIH," *The New England Journal of Medicine* (December 13, 2016) (online at: <http://www.nejm.org/doi/full/10.1056/NEJMp1615745>).


2. As HHS Secretary, would you commit to proposing budgets that take full advantage of funding streams authorized in the 21st Century Cures Act?⁹³
3. As HHS Secretary, would you commit to providing the Director of the NIH, as well as all the other institute directors and the FDA Commissioner, with the tools, infrastructure, and other support necessary to carry out their agencies' missions?

CONCLUSION

The HHS Secretary is responsible for programs that provide high quality, accessible, and affordable health care to millions of Americans. The Department sets basic standards for health care coverage under the Affordable Care Act, pays for billions of dollars-worth of medical procedures and pharmaceuticals via the Medicare and Medicaid programs, enforces regulations covering everything from food, drug, and medical device safety to nursing home quality, runs the nation's premier medical research institutions, and is responsible for day-to-day public health promotion and for responding to urgent health care emergencies in the U.S. and abroad.

It is critical that the HHS Secretary understand the importance of these programs and implement and enforce them effectively and efficiently, without ideological or partisan bias. I look forward to your confirmation hearing, and to receiving the answers to my questions so that I can fully evaluate your qualifications and preparedness.

Sincerely,


Elizabeth Warren
United States Senator

⁹³ H.R. 34, "21st Century Cures Act" (online at <https://www.congress.gov/bill/114th-congress/house-bill/34/text>).