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November 22, 2019

Brett Giroir, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Giroir:

I write regarding your recent appointment to serve as Acting Commissioner of the U.S. Food and Drug Administration (FDA), the federal agency responsible for safeguarding the public health based on science and free from political interference. I have concerns about your appointment because during your time as the Assistant Secretary for Health at the Department of Health and Human Services (HHS), you have undermined evidence-based programs and promulgated policies based on political ideology—behavior that is antithetical to the very mission of HHS and the agency you are now charged with leading. Given your record of service at HHS, Congress and the public deserve assurances that you are committed to evidence-based decision-making and to upholding the scientific integrity of the FDA.

In your role as the Assistant Secretary for Health, you are responsible for overseeing critically important offices, including the Office of Women's Health, the Office of HIV/AIDS and Infectious Disease Policy, and the Office of Population Affairs. Though you were confirmed by the Senate to this position last year, I voted against your nomination because I was unconvinced that you would promote the use of evidence-based health policy in your role overseeing the programs of these offices.

During your confirmation process, I sought your commitment to advocate for and sustain evidence-based public health practices as Assistant Secretary for Health. In response to my questions for the record on topics ranging from reproductive health, to contraception, to HIV/AIDS, you committed to “implement[ing] evidence-based programs,” and “applying evidence and common sense to our policymaking process.”¹ Despite these “assurances,” HHS under your leadership has systematically rolled back evidence-based programs proven to improve health outcomes.

In response to my question regarding the Title X Family Planning Program (Title X), for example, you answered that you were “committed to promoting the public’s health and applying evidence and common sense to our policymaking practice.”² Yet, as Assistant Secretary, you oversee the Office of Population Affairs, which has worked to dismantle the Title X Federal

¹ Answers to Questions for the Record from Dr. Brett Giroir to Senator Elizabeth Warren, August 1, 2017.

² Answers to Questions for the Record from Dr. Brett Giroir to Senator Elizabeth Warren, August 1, 2017.

Family Planning Program. Title X is the only federal program dedicated to providing family planning services to people with low incomes. In keeping with longstanding medical, ethical, and legal standards of health care, Title X has funded basic and comprehensive reproductive health services for millions of low income Americans—including cancer screenings, sexually transmitted infections (STI) testing, and birth control—for nearly 50 years.³ But under your leadership, HHS undermined the program by implementing a rule that imposes a “gag rule” on Title X providers, loosens the evidence-based quality requirements that have defined the program from its inception, and reduces access to care for patients.⁴ As a result of the rule, a number of health care providers have withdrawn from the program. Instead, the agency has awarded family planning dollars to the Obria Group,⁵ which does not provide hormonal birth control⁶ or condoms⁷ and promotes a fertility app that “sows doubt about the pill.”⁸ In pursuing these changes, you ignored significant opposition from well-respected medical organizations, including the American Medical Association.⁹

The Office of Population Affairs also administers the Teen Pregnancy Prevention Program, an “evidence-based program that funds diverse organizations that are working to prevent teen pregnancy.”¹⁰ Comprehensive sex education programs “delay sexual debut, reduce frequency of sex and number of partners, increase condom or contraceptive use, or reduce sexual risk-taking.”¹¹ But in your time at HHS, the Department has re-written the rules of the program to emphasize abstinence-only programming, which has proven to be ineffective, if not

³ Planned Parenthood Action Fund, “Title X: America’s Family Planning Program,” <https://www.plannedparenthoodaction.org/issues/health-care-equity/title-x>.

⁴ The Title X rule undermines the program’s ability to provide high-quality health services to its millions of patients by imposing a “gag rule” that prohibits Title X providers from referring patients for abortion services, even if patients specifically request a referral, and even if counseling on parenting and adoption has also been offered. The rule also weakens the standards of care typically required of Title X providers, paving the way for unqualified providers to access Title X funds. The rule also directly attacks Planned Parenthood by requiring facilities that receive Title X funds to be physically and financially separate from facilities that perform abortions, even though Title X funds are already prohibited from being used for abortions. As a result of the rule, many Title X providers and states have been forced out of the program. See U.S. Senator Elizabeth Warren, “Senators Warren, Hassan, and Colleagues Request HELP Hearing to Assess the Impacts of Title X Rule,” Press Release, March 19, 2019, <https://www.warren.senate.gov/newsroom/press-releases/senators-warren-hassan-and-colleagues-request-help-hearing-to-assess-the-impacts-of-title-x-rule>.

⁵ The New York Times, “Trump Administration Gives Family Planning Grant to Anti-Abortion Group,” Kenneth P. Vogel and Robert Pear, March 29, 2019, <https://www.nytimes.com/2019/03/29/us/politics/trump-grant-abortion.html>.

⁶ Rewire News, “An Anti-Choice Group Pledged It Would ‘Never’ Provide Contraception as It Pursued Title X Funds,” Dennis Carter, May 14, 2019, <https://rewire.news/article/2019/05/14/an-anti-choice-group-pledged-it-would-never-provide-contraception-as-it-pursued-title-x-funds/>.

⁷ Rewire News, “Federally Funded Obria Prescribes Abstinence to Stop the Spread of STDs,” Sarah Varney, October 8, 2019, <https://rewire.news/article/2019/10/08/federally-funded-obria-prescribes-abstinence-to-stop-the-spread-of-stds/>.

⁸ The Guardian, “Anti-Abortion Group Uses Federal Grants to Push Controversial Fertility App,” Jessica Glenza, July 29, 2019, <https://www.theguardian.com/society/2019/jul/29/us-federal-grants-femm-app-natural-birth-control>.

⁹ American Medical Association, “We Cannot Let Changes to Title X Put Women’s Health at Risk,” Barbara L. McAneny, March 5, 2019, <https://www.ama-assn.org/about/leadership/we-cannot-let-changes-title-x-put-women-s-health-risk>.

¹⁰ U.S. Department of Health and Human Services, Office of Adolescent Health, “Teen Pregnancy Prevention Program (TPP),” <https://www.hhs.gov/ash/oah/grant-programs/teen-pregnancy-prevention-program-tpp/index.html>.

¹¹ Guttmacher Institute, “What is Behind the Declines in Teen Pregnancy Rates,” Heather D. Boonstra, September 3, 2014, <https://www.guttmacher.org/gpr/2014/09/what-behind-declines-teen-pregnancy-rates>.

detrimental, to efforts to reduce pregnancy and sexually transmitted infections.¹² Earlier this year, HHS announced that it diverted federal funding from evidence-based programs to providers that promote ineffective abstinence-only education and offer non-FDA-approved medication abortion reversal treatments.¹³ These actions violate your written commitment to me that you “intend[ed] to develop and implement evidence-based policies and programs to, among other things, decrease unintended pregnancies, and STIs among all Americans, especially among teenagers.”¹⁴

In answering my question about the HIV/AIDS Program, you also committed that you would “seek a broad diversity of opinions and include them in the public health decision making process.”¹⁵ But at HHS, you directly spearheaded the administration’s efforts to defund critical research addressing HIV and other diseases—ignoring the opposition of the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the American Association for the Advancement of Science, and 60 other scientific, academic, and medical associations and research institutions that such a rule “would severely obstruct research that is necessary for the development of new treatments for a wide range of serious diseases.”¹⁶

As Acting Commissioner of the FDA, you are responsible for decisions that affect the health and safety of every American. Therefore, I am seeking assurances that you will set aside politics and commit to evidence-based policy making during your tenure at the agency. You have not lived up to the commitments you made to Congress and the public prior to being confirmed to your current position at HHS, and you must do better at the FDA. I look forward to receiving a written response that confirms your commitment to evidence-based policymaking at the agency by November 29, 2019.

Sincerely,



Elizabeth Warren
United States Senator

¹² Guttmacher Institute, “The Teen Pregnancy Prevention Program Was on the Right Track, Now It’s Being Dismantled,” May 24, 2018, <https://www.guttmacher.org/article/2018/05/teen-pregnancy-prevention-program-was-right-track-now-its-being-dismantled>.

¹³ Rewire News, “HHS Awards Nearly \$1.5 Million in Teen Pregnancy Prevention Funding to Anti-Choice Organizations,” Sony Salzman, July 23, 2019, <https://rewire.news/article/2019/07/23/hhs-awards-nearly-1-5-million-in-teen-pregnancy-prevention-funding-to-anti-choice-organizations/>.

¹⁴ Answers to Questions for the Record from Dr. Brett Giroir to Senator Elizabeth Warren, August 1, 2017.

¹⁵ Answers to Questions for the Record from Dr. Brett Giroir to Senator Elizabeth Warren, August 1, 2017.

¹⁶ Letter from Academic Pediatric Association, et al, to Senator Mitch McConnell, Senator Charles E. Schumer, Representative Paul Ryan, and Representative Nancy Pelosi, September 10, 2018.