U.S. Department of Health and Human Services
Office of the Assistant Secretary for Planning and Evaluation
Strategic Planning Team
200 Independence Avenue, SW, Room 415F
Washington, DC 20201

27 October 2017

Public Comment Re: HHS Strategic Plan FY 2018-2022

Dear U.S. Department of Health and Human Services,

Treatment Action Group (TAG) is pleased to submit the following comment to the Strategic Planning Team at the Office of the Assistant Secretary for Planning and Evaluation regarding the HHS Strategic Plan FY 2018-2022. As an organization concerned with access to better treatment, prevention, and care for HIV, tuberculosis (TB), and hepatitis C virus (HCV), we believe the HHS Strategic Plan can set a precedent for reducing the burden of disease nationally through its focus on access to affordable treatment, advancement of research, implementation of evidence-based interventions, expansion of populations served, and inclusion of all stakeholders.

We compliment the comprehensive nature of these activities, from addressing social determinants of health, to improving access to affordable and quality care under the American healthcare system, to applying research and promotion of basic sciences, to the inclusion of all relevant stakeholders. However, we are concerned with the overwhelming number of mentions of faith-based organizations, which may limit the capacity to provide care and treatment for all vulnerable populations. In order to fulfill the multiple aims for reducing health disparities, care and treatment must include the LGBTQ community and migrant populations, which constitute a substantial portion of the population who face health disparities within the American healthcare system. The religious undertone of the document hinders the ability to input language on sex and sexually transmitted infections, ultimately excluding a large number of Americans at risk that need critical interventions to address certain prominent conditions. We urge HHS to expand the populations to include the LGBTQ community and migrant populations and ensure that solutions provided by faith-based organizations are evidence-based.

While the strategic plan emphasizes reducing consumer costs and promotion of price transparency for consumers, HHS must include additional strategies to reduce healthcare costs themselves. This includes drug prices, which are beyond what the market can reasonably bear, and are one of the most significant drivers of public and private coverage costs in the U.S. In particular, where the U.S. public, through government-funded research, has supported the development of medicines, diagnostics, biologics, or vaccines or preventive therapies, HHS has a special role to play in acknowledging the contributions of public awards, tax breaks, and other incentives in bringing these products to market and ensuring affordability and accessibility to avoid the public missing out on or paying twice for such interventions.

To improve language in the strategic plan and make it more comprehensive and, in particular, for our three issue areas, we offer the following overarching comments, as well as detailed comments and revisions to specific aims/objectives in Table 1 below:

1. While we commend HHS in the inclusion of promoting healthy lifestyle behaviors, the strategic plan should stress interventions that can fulfill these "healthy lifestyle behaviors," including pre-exposure prophylaxis as an evidence-based component of safer sex practices, and harm reduction strategies—especially for adolescents—such as promotion of condom use, syringe exchange/distribution programs, and expanded access to medically assisted treatment for opioid use disorders, such as buprenorphine.

2. The re-establishment of the Office of National AIDS Policy (ONAP) under the White House Domestic Policy Council, has been without leadership and evidence of White House administration coordination since President Trump took office. ONAP is critical to the implementation of the National HIV/AIDS Strategy, which has played a considerable role in meeting scientifically validated and cost-effective HIV incidence and health outcomes. These include maximizing the number of people living with and vulnerable to HIV infection who are accessing care and utilizing evidence-based tools, such as antiretroviral therapy or pre-exposure prophylaxis.

3. With the emphasis on resistant bacteria throughout the document, clarification is needed on the definition of healthcare-associated infections such as in Objective 1.2. The threat of drug resistance is aggravated not only by the overuse of prescription drugs, but also through the use of outdated and inadequate drug regimens, particularly for TB. HHS should explicitly include prevention and treatment of drug resistant TB in sections mentioning antimicrobial resistance, especially in the context of global health security and emerging and re-emerging disease threats.

4. HHS must remain committed to developing and implementing the use of new diagnostics for bacterial infections and antibiotics for drug-resistant variants, particularly tuberculosis and gonorrhea in the United States. Stringent regulatory review of new diagnostics and antimicrobial agents by the U.S. Food and Drug

Administration should also remain an HHS priority, to ensure U.S. population safety, efficacy, and clinical best practices.

5. We applaud HHS for incorporating pregnant women as a key population that require additional, and sometimes alternative, care and treatment, and efforts to support the healthy development and wellbeing of children and youth. However, services for pregnant and lactating women must also include measures to protect mothers and their children from infectious diseases. This should include i) robust primary prevention programs (including TB and HIV preventive therapy for pregnant women as indicated), ii) strong test and treat strategies for TB, HIV, and HCV to protect the health of the mother and limit mother-to-child transmission of infection, and iii) evidence-based interventions including medically assisted treatment for pregnant women and mothers with opioid use disorders.

6. While we appreciate the inclusion of a section on substance use and substantial statements on addressing the opioid crisis, we urge HHS to integrate explicit mention of targeting HCV transmission, which is tightly linked with the ongoing opioid epidemic. Prevention and harm reduction programs such as expansion of safe consumption spaces and syringe exchange programs, and access to affordable naloxone to prevent opioid overdose-related deaths are essential to reducing HCV rates and effectuating the National Academies of Sciences, Engineering and Medicine's "A National Strategy for the Elimination of Hepatitis B and C: Phase Two Report".

Thank you for the opportunity to comment. Please direct any questions regarding this submission to Erica Lessem at erica.lessem@treatmentactiongroup.org.

Respectfully submitted,
Treatment Action Group

Table 1. Revisions to specific aims/objectives

Page/ line #	HHS Content	Comments
HIV		
Pg. 24, line 606	Improve HIV viral suppression and prevention by increasing engagement and re-engagement activities for screening, care, treatment and support services	HHS should seek to re-establish the Office of National AIDS Policy under the current White House administration and continue advancing the National HIV/AIDS Strategy. HHS must commit to providing robust primary HIV prevention, including comprehensive sex education and access to pre-exposure prophylaxis, particularly for uninsured or under-insured U.S. residents vulnerable to HIV infection.
Pg. 52, line 1368	Support basic science and applied prevention and treatment research on approaches to reduce the global burden of HIV, viral hepatitis, enteric and respiratory diseases, tuberculosis, malaria, and neglected tropical diseases	We applaud the support for basic and applied research into HIV, viral hepatitis, tuberculosis, and other conditions.
Tuberculosis/antimicrobial resistance		
Pg. 10, line 228	Align incentives and promote the use of evidence-based guidelines, strategies, innovation, and public–private partnerships to identify, target, and prevent healthcare- associated infections, antibiotic resistance, and other adverse events in all healthcare settings	HHS must ensure innovations that are available globally to combat antibiotic resistance, including antibiotics and fixed dose formulations of combinations of TB medicines, are available in the U.S.—especially so when they have been developed using U.S. funding.
Pg. 11, line 239	Support research and innovation to strengthen evidence-based recommendations, address quality gaps and safety risks for healthcare-associated conditions, develop improved methods and strategies to prevent healthcare-associated infections and combat antibiotic resistance, and translate this knowledge and evidence into practical tools, training, and other resources to accelerate progress to improve quality and patient safety	In accordance with the National Action Plan for Combating Multidrug-Resistant Tuberculosis, HHS should explicitly add language pertaining to multidrug-resistant tuberculosis, the leading cause of AMR death worldwide, and a driver of outsized healthcare costs in the U.S. (CDC estimates one case of extensively drug-resistant TB in the U.S. costs an average of $678,000 to treat, with treatment lasting over 2 years.)

Pg. 46, line 1180	Support the development, implementation, and evaluation of new laboratory technologies and their use for emerging infectious diseases, antimicrobial resistance, food safety, pharmaceutical safety, chronic disease risk factors, and environmental biomonitoring	There should be a clear message here for developing and implementing the use of new antibiotics (in addition to diagnostics), particularly for gonorrhea.
Services/care management		
Pg. 21, line 509	Increase awareness of the importance of healthy lifestyle behaviors among patients and caregivers for risk reduction of chronic conditions and other illnesses, including for those with or at risk of Alzheimer's disease and other dementias, across the lifespan	HHS should include specific interventions that can fulfill "health lifestyle behaviors," such as i) pre-exposure prophylaxis for HIV as an evidence-based component of safer sex practices and ii) scale up of prevention and harm reduction programs for people who use drugs, including the expansion of safe consumption spaces and syringe exchange programs, and access to affordable naloxone to prevent opioid overdose-related deaths.
Pg. 24, line 601	Support early detection and treatment of communicable and chronic diseases (heading)	We commend HHS for including specific strategies for detecting and treating HIV and hepatitis C. With the challenge of combatting drug-resistant tuberculosis threatening progress towards elimination, specific language on implementing evidence-based prevention, diagnosis, and treatment strategies and ensuring adequate resources to do so are essential.
Research		
Pg. 23, line 574	Develop a comprehensive portfolio of safe and effective vaccines, therapeutics including both pharmaceuticals and non-pharmaceuticals, diagnostics, and medical devices against a broad array of communicable diseases and chronic conditions	Development should be based on target product profiles, which include safety and efficacy, but also ease-of-administration and consumer acceptability.
Pg. 53, line 1384	Support and facilitate the adoption of innovative pharmaceutical technology to modernize product development and manufacturing, ensuring the	We support these measures, and encourage HHS to explore mechanisms with FDA to allow for importation of quality-assured products available on

	consistent supply of high quality medicine for patients, and encourage the development of low-cost, high quality generic pharmaceuticals	the global market.
Costs		
Pg. 8, line 173	Strengthen coverage options to reduce consumer costs (heading)	We appreciate HHS' plans for interventions to reduce consumer health care costs while promoting quality, but urge HHS to include strategies to reduce overall healthcare costs, including drug prices, which are beyond what the market and public can reasonably bear and are one of the most significant drivers of public and private coverage costs in the U.S. This is especially so for technologies and interventions developed with public funding.