



February 28, 2017

The Honorable Tom Price, M.D.
Secretary of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

VIA: E-MAIL

Re: On the Essential Role of the Offices of Minority Health as part of the Department of Health and Human Services in Increasing the Public Health of All Americans, Including as part of the Food and Drug Administration's Commitment to the Safety and Efficacy of Medicines in All Populations

Dear Secretary Price:

We the National Medical Association, National Hispanic Medical Association, and National Council of Asian Pacific Islander Physicians, come together on behalf of our patients. We have found that many Black, Hispanic, Asian, Native Hawaiian, and Pacific Islander patients and communities experience suboptimal health outcomes. We write to you out of concern for them. Since before the Affordable Care Act (ACA) we have worked with the Office of Minority Health (OMH), Department of Health and Human Services (HHS), and subsequently, with the additional Offices of Minority Health formed under the ACA. They are our conduit within HHS to work on reducing health disparities for our vulnerable populations. We urge you to use your leadership to do all you can to ensure that all of the Offices of Minority Health remain, and remain funded and supported within your Department.

In addition to providing care as doctors, we contribute to public health through our advocacy, our programs to tackle health disparities, and through partnering with HHS and policy makers. We write to you to open a dialogue that we hope will continue through the years - just as some of our organizations have enjoyed for decades, irrespective of executive administration or political party.

While at no time in American history have minority populations enjoyed health equity, the "beginning" of the recognition of health disparities in public health policy came with the landmark Heckler Report released by then Secretary of Health Margaret Heckler in 1984 during the second Reagan Administration. The Heckler Report led to the establishment of the first Office of Minority Health (OMH) in 1986, with the mission to improve "the health of racial and

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ethnic minority populations through the development of health policies and programs that will help eliminate health disparities.” It was then established as law by Congress in 1990 with the Minority Health Improvement Act, expanding OMH’s work with state-level offices working to improve health disparities.

From 1986 until today, OMH has been *our* partner in HHS. OMH recognizes that without acknowledgement and awareness of the problems of health disparities, there can be no solutions. OMH has invested in community research to fund studies on reducing health disparities. OMH has been our voice within HHS on how their policies are impacting communities across the country, from San Francisco Chinatown, to inner cities in Chicago, to rural communities and tribal lands. We have partnered with them in programs and initiatives that have improved the health of our communities.

The Affordable Care Act was passed in 2010 with language that spoke to a more efficient and nuanced health care system, as well as policies that would enhance, support, and carry out the objective of eliminating health disparities. This included the reauthorization of OMH itself, as well as the creation of individual OMH’s at the six HHS agencies, and the establishment of the National Institute of Minority Health and Health Disparities as an institute within the National Institutes of Health (NIH). The creation of these institutions are steps toward that mission of eliminating health disparities; allowing them to be dismantled, as part of any repeal efforts, would be a significant loss.

We have had the honor of working directly with Food and Drug Administration’s (FDA) OMH director, Dr. Jonca Bull, and she has supported the interests of minority populations well. Within FDA, Dr. Bull and the FDA-OMH share our concern that drug development must be more inclusive to all Americans across the development life cycle, from concept to market. Our membership includes physicians that work in regulatory capacities, in industry, as site based researchers, and as prescribing physicians. We must make every effort to sustain the FDA-OMH especially at a time when much of the discussion is focused on “streamlining”, “deregulating”, and speeding up the process for drug development. While expediting the approval of new life saving medications is a desirable objective, it should be recognized that the mission of OMH helps us avoid potential unintended consequences of increasing morbidity and mortality in significant subsections of our diverse population.

For as long as industry and government have aligned to make drugs available to patients, there has been a tension associated with speed versus safety. Efforts to achieve adequate minority participation

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in drug trials are often seen as barriers to speed and traditionally have been limited or nonexistent. This contributes to a lack of data guiding the safe and effective use of drugs in minority patients. This absence of data has not limited the marketing of drugs for use in minority patients, thus creating the conditions for potential disparities in health associated with inappropriate drug treatment. Therefore, it is imperative that the liaison with the FDA-OMH be maintained to ensure the interests of all patients are represented throughout the process.

We anticipate the recent approval of the 21st Century Cures Act will provide benefits to patients. We maintain our concern for the impact of off label use especially under circumstances of inadequate clinical trial data supporting the label. In our joint 2014 letter on the Food and Drug Administration Safety and Innovation Act, we expressed the importance of educating physicians on prescribing drugs to minorities even when these patients were not sufficiently represented in trials. We continue to advocate for data transparency that allows doctors to make the best decision possible on the safe and effective use of available medicines. We welcome and continue to advocate for better standards for minority inclusion. We must continue to progress from a “one size fits all” strategy in drug therapy. Indeed, we are encouraged by the Precision Medicine Initiative which seeks recruitment of a cohort that represents the diversity of the American patient population.

As doctors who represent minority communities, we look forward to opening a dialogue with you. Secretary Price, we strongly urge you to support the Offices of Minority Health at FDA and throughout the Department of Health and Human Services, empowering them to fulfill their mission for the good of all Americans.

Sincerely,



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cc: The Honorable Paul Ryan, Speaker of the House of Representative
The Honorable Mitch McConnell, Majority Leader, U.S. Senate
The Honorable Charles Schumer, Minority Leader, U.S. Senate
The Honorable Nancy Pelosi, Minority Leader, U.S. House of Representatives
The Honorable **Judy Chu**, Congressional Asian Pacific American Caucus
The Honorable Michelle Lujan Grisham, Congressional Hispanic Caucus
The Honorable Cedric Richmond, Congressional Black Caucus
Stephen Ostroff, M.D., Acting Commissioner of Food and Drugs