

May 4, 2022

The Honorable Raul Ruiz  
U.S. House of Representatives  
2342 Rayburn House Office Building  
Washington, DC 20515

The Honorable Larry Bucshon  
U.S. House of Representatives  
2313 Rayburn House Office Building  
Washington, DC 20515

Dear Representatives Ruiz and Bucshon:

On behalf of our physician and medical student members, the American Medical Association (AMA) is writing in support of H.R. 5030, the “Diversifying Investigations Via Equitable Research Studies for Everyone Trials Act,” or the “DIVERSE Trials Act.” This bill would improve diversity in clinical trials and data collection for COVID-19 and future public health threats to help address issues surrounding social determinants of health. The AMA believes that racial and ethnic disparities should be eliminated in health care and this bill would bring us a step closer to helping make health care more equitable.

Historically, clinical trials funded by the National Institutes of Health (NIH) failed to enlist participants who represented the individuals most affected by a particular disease, condition, or behavior. Frequently, clinical trials relied almost exclusively on White male study participants.<sup>1</sup> “This shortcoming has created gaps in our understanding of diseases and conditions, preventive factors, and treatment effectiveness across populations. These gaps in knowledge can impede the quality of health care decision-making, ability to counsel people on ways to reduce their risk, optimal treatment responses, and even the development of more effective medications or interventions.”<sup>2</sup> Unfortunately, this shortcoming can still be seen today. For example, in 2015, 15% of NIH-funded studies had less than 30% women participants.<sup>3</sup> Moreover, less than 15% of randomized clinical trials published in 2015 and 2019 reported the socioeconomic statuses of participants.<sup>4</sup> Furthermore, there are a multitude of disparities when doing research for specific diseases such as pancreatic cancer trials in which “Black patients comprised just 8.2% of the 8,429 participants while they make up 12.4% of pancreatic cases in the United States.”<sup>5</sup> A similar disparity exists for the Hispanic population: “6% of participants were classified as Hispanic while making up 8.5% of U.S. cases.”<sup>6</sup>

The DIVERSE Trials Act would take important steps to ensuring that our clinical trials are more representative of our patient population by issuing guidance that addresses how to conduct decentralized clinical trials with meaningful demographic diversity, including guidance for clinical trials that are

---

<sup>1</sup> <https://www.nimhd.nih.gov/resources/understanding-health-disparities/diversity-and-inclusion-in-clinical-trials.html>.

<sup>2</sup> <https://www.nimhd.nih.gov/resources/understanding-health-disparities/diversity-and-inclusion-in-clinical-trials.html>.

<sup>3</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5908758/>.

<sup>4</sup> <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780381>.

<sup>5</sup> <https://www.healio.com/news/gastroenterology/20210517/pancreatic-cancer-trials-fall-short-on-diversity>.

<sup>6</sup> Id.

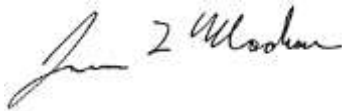
The Honorable Raul Ruiz  
The Honorable Larry Bucshon  
May 4, 2022  
Page 2

executed through a broad spectrum of options, such as telemedicine or other mobile or digital technologies. Moreover, grants would be issued to support community education, outreach, and recruitment activities for clinical trials with respect to drugs, including vaccines for diseases or conditions which have a disproportionate impact on underrepresented populations, including COVID-19. Additionally, laboratories that are subject to the reporting requirements under the Coronavirus Aid, Relief, and Economic Security Act would be required to include information to enhance existing COVID-19 data collection activities and to advance policies to address social determinants of health. These provisions would help to increase the overall effectiveness of drugs and vaccines.

We cannot afford to have continued underrepresentation of diverse populations in clinical trials, which can result in the development of treatments that fail to address health disparities and inequalities across the United States.<sup>7</sup> People experience the same disease differently based on a variety of lived experiences, conditions, and characteristics like race and ethnicity, age, sex, and sexual orientation.<sup>8</sup> It is therefore important that all communities are included in clinical trials so that all communities can benefit from scientific advances. As such, the DIVERSE Trials Act is a positive step towards broadening enrollment practices of clinical trials to reflect clinically relevant populations which will increase the effectiveness of our medicine and help to address social determinants of health.

The AMA commends your ongoing commitment to this important issue, and we look forward to working with you to further advance this legislation.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large initial "J" and "M".

James L. Madara, MD

---

<sup>7</sup><https://science.nichd.nih.gov/confluence/display/newsletter/2021/01/27/The+Importance+of+Diversity+in+Clinical+Trials>.

<sup>8</sup><https://www.nimhd.nih.gov/resources/understanding-health-disparities/diversity-and-inclusion-in-clinical-trials.html>.