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June 5, 2020

The Honorable Mitch McConnell
Majority Leader
United States Senate
S-230, The Capitol
Washington, D.C. 20515

The Honorable Charles Schumer
Minority Leader
United States Senate
S-221, The Capitol
Washington, D.C. 20515

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-232, The Capitol
Washington, D.C. 20515

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
H-204, The Capitol
Washington, D.C. 20515

Dear Majority Leader McConnell, Speaker Pelosi, Minority Leader
Schumer, and Minority Leader McCarthy:

On behalf of the American Heart Association (AHA) and its more than 40 million volunteers and supporters, we thank you for what you have done so far in responding to the COVID-19 pandemic. I write today in support of new legislation, HR 6443, the Medical Manufacturing, Economic Development, and Sustainability Act of 2020 (MMEDS Act) and its provisions that would further help protect aging Americans, African American, Hispanic Americans, and Native Americans—those who face disproportionate risk of severe illness and death in the COVID-19 pandemic due in large part to higher rates of underlying chronic diseases.

Cardiovascular disease (CVD) is the number one killer in the United States and worldwide, accounting for 17.3 million deaths globally each year. Early reports and data show that people with CVD face increased health risks from COVID-19, and patients with COVID-19 infection are at greater risk of developing severe medical complications including heart failure, stroke, and death. Among those discoveries, people over age 65 with coronary heart disease or hypertension may be more likely to be infected and to develop severe symptoms. Forty percent of hospitalized COVID-19 patients had CVD or cerebrovascular disease. The situation is even more dire for communities of color, where data indicate that minorities are more susceptible to coronavirus infections suffer higher rates of death.

On February 26, 2019, the American Heart Association released a “Call to Action,” which concludes “there is an urgent need for action to improve innovation in, treatment of, and payment for cardiovascular health.” Among the underlying reasons for relatively low CVD innovation, the Call to Action emphasizes the under-investment in CVD research at the National Institutes of Health (roughly 5 percent of the overall budget), the complexity, size, and high cost of CVD clinical trials, and lack of market incentives to develop CVD treatments.

Provisions of the MMEDS Act would address under-investment and insufficient innovation in CVD and chronic disease products through three relatively modest improvements in existing Biomedical Advanced Research and Development Authority (BARDA) regulations:

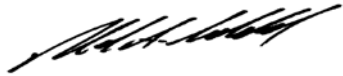
1. **BARDA-Led “Strategic Initiative.”** The MMEDS Act empowers and directs BARDA to lead a public-private “Strategic Initiative” to develop innovative, widely-available “population health products to address CVD and other chronic diseases, strengthen the U.S. medical stockpile of these products, and materially advance our national preparedness for future epidemics and pandemics.
2. **Collaboration in Approval and Delivery of Population Health Products.** The MMEDS Act also directs BARDA to collaborate with the Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS), Department of Defense, Veterans Administration, and other federal agencies to promote streamlined approval and expedited distribution of new population health products to patients.
3. **GAIN Act Study.** Finally, the MMEDS Act directs the Secretary of Health and Human Services to recommend to Congress within 90 days whether the GAIN Act should be expanded to include a period of additional exclusivity for successful development of population health products.

COVID-19 has heightened public attention to the need to address health disparities and the underlying chronic diseases including CVD that disproportionately affect people of color and seniors. The MMEDS Act’s proposed regulatory changes, while relatively modest, represent a national prioritization and a public-private commitment to reinvigorate innovation and production of widely available population health products to address CVD and the chronic diseases that remain the leading causes of death.

Thank you again for what Congress has done thus far in COVID-19 response and recovery efforts to protect vulnerable communities. If you

have any questions or need further information, please contact Emily Holubowich, Vice President of Federal Advocacy at emily.holubowich@heart.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark Schoeberl', with a stylized flourish at the end.

Mark Schoeberl
Executive Vice President, Advocacy
American Heart Association