



November 12, 2020

The Honorable Andrew Cuomo, Chair
The Honorable Asa Hutchinson, Vice Chair
National Governors Association
444 North Capitol Street, Suite 267
Washington, DC 20001

Dear Governors Cuomo and Hutchinson,

On behalf of the thousands of scientists in the biopharmaceutical industry working around the clock to develop vaccines and treatments to combat COVID-19, I want to reinforce with you and all our nation's governors that the highest priority for the Biotechnology Innovation Organization (BIO) and our member companies is to ensure the safety and efficacy of these medicines under development. Like you, BIO believes the only way to halt the spread of COVID-19 is to trust in the science and stand by our medical experts. However, we are concerned about the unintended consequences that could occur from additional state-level vaccine safety and efficacy reviews. Our greatest concern is the delay in access to FDA-approved COVID-19 vaccines that may result from such efforts, which then would prolong the length and severity of the pandemic.

As a physician, researcher, and former FDA regulator, I can tell you from experience that FDA's review of vaccines and therapies is conducted by leading scientific and clinical experts who ensure a thorough, time-intensive analysis of safety and efficacy before a treatment is made available to the public. Recognizing the heightened importance for transparency in the context of this ongoing pandemic, there has been an unprecedented amount of data sharing and opportunities for scientific and medical experts across the country to provide input and evaluate information relating to the vaccines being developed. While states undoubtedly have numerous experts to perform such reviews, a separate, formal review is unlikely to provide any meaningful additional benefit. And it would require the establishment of procedures and protocols around conflicts of interest and the handling of confidential clinical trial data that could be time intensive and further delay access. Federal agencies have long-established processes and protocols in place to deal with these issues that newly established state entities may not be able to replicate in time.

I also want to express BIO's confidence that the FDA and CDC have put in place processes divorced from political pressure and that provide opportunities for external expert review. The FDA's Vaccine and Related Biological Products Advisory Committee (VRBPAC) and the CDC's Advisory Committee on Immunization Practices (ACIP) are non-partisan, non-political scientific advisory committees charged with ensuring vaccines are safe, efficacious, and



recommended for appropriate use. The volunteer members of these panels are international leaders in their fields of science and clinical medicine. Since the COVID-19 pandemic began, the VRBPAC has held multiple public meetings to discuss its recommended approach for vaccine approval and to receive public comments. ACIP convened a COVID-19 Vaccine Workgroup in April, which has been meeting weekly since. Additionally, since June, ACIP has held monthly public meetings to discuss COVID-19 vaccine development and prioritization.

I have stated publicly that politics must not interfere with, or undermine, the public's faith in the rigorous and independent scientific review process that has long been the hallmark of both FDA and CDC. I also share the concerns of you and many of your fellow Governors regarding the appearance of undue political pressure on the process. I have spoken out against it, but I want to reiterate our firm commitment to you that BIO and our member companies put science and patients first. This was recently expressed in a public pledge by our member companies working on all leading COVID-19 vaccine candidates.

BIO appreciates the hard work and leadership you and all the governors have shown in combatting this pandemic. We stand ready to partner with the National Governors Association and governors from across our great country to ensure the public has every confidence in the safety and efficacy of vaccines and treatments being developed by our member companies. Please consider our industry an ally and a committed partner in your efforts to build vaccine confidence and equitably distribute COVID-19 vaccines to every community in the United States.

Sincerely,

A handwritten signature in black ink, appearing to read "MMH", with a long horizontal line extending to the right.

Michelle McMurry-Heath, M.D., Ph.D.
President & CEO

CC: Bill McBride, Timothy Blute, Kate Johnson, Maribel Ramos, Kate Bukowski