Peter Marks, MD, PhD
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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

March 28, 2025

Sara Brenner, MD, MPH
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Dr. Brenner:

It is with a heavy heart that I have decided to resign from FDA and retire from federal service as Director of the Center for Biologics Evaluation and Research effective April 5, 2025. I leave behind a staff of professionals who are undoubtedly the most devoted to protecting and promoting the public health of any group of people that I have encountered during my four decades working in the public and private sectors. I have always done my best to advocate for their well-being and I would ask that you do the same during this very difficult time during which their critical importance to the safety and security of our nation may be underappreciated.

Over the past years I have been involved in enhancing the safety of our nation's blood supply, in advancing the field of cell and gene therapy, and in responding to public health emergencies. In the last of these, during the COVID-19 pandemic I had the privilege of watching the vision that I conceived for Operation Warp Speed in March 2020 in collaboration with Dr. Robert Kadlec become a reality under the leadership of HHS Secretary Azar and President Trump due to the unwavering commitment of public servants at FDA and elsewhere across the government. At FDA, the tireless efforts of staff across the agency resulted in remarkably expediting the development of vaccines against the virus, meeting the standards for quality, safety, and effectiveness expected by the American public. The vaccines undoubtedly markedly reduced morbidity and mortality from COVID-19 in the United States and elsewhere. Many of these same individuals applied learnings from the pandemic during a flawless response helping to facilitate the rapid control of the mpox epidemic in the United States during 2022. Individuals who participated in these responses remain at the ready to address the infectious threats that undoubtedly will confront us in the coming years, including H5N1, which is now on our threshold.

Efforts currently being advanced by some on the adverse health effects of vaccination are concerning. The history of the potential individual and societal benefits of vaccination is as old as our great nation. George Washington considered protecting his troops in Cambridge, Massachusetts against smallpox early in the revolutionary war so that they would not be susceptible to infection by British troops infiltrating the ranks, and later in the war in February 1777 while encamped in Morristown, NJ, he went on to have the courage and foresight to sign an order requiring inoculation of his troops against smallpox. Subsequently, refinement of the smallpox vaccine combined with a widespread vaccination campaign resulted in the eradication of smallpox from the globe. The application of the remarkable scientific advances of Drs. Salk and Sabin's vaccines led to the elimination of polio in the United States. And these are just effects of two of the vaccines that have been associated with saving millions of lives.

The ongoing multistate measles outbreak that is particularly severe in Texas reminds us of what happens when confidence in well-established science underlying public health and well-being is undermined. Measles, which killed more than 100,000 unvaccinated children last year in Africa and Asia owing to pneumonitis and encephalitis caused by the virus, had been eliminated from our shores. The two-dose measles, mumps, rubella vaccine regimen (MMR) using over the past decades has a remarkably favorable benefit-risk profile. The MMR vaccine is 97% or more effective in preventing measles following the two-dose series, and its safety has been remarkably well studied. Though rarely followed by a single fever-related seizure, or very rarely by allergic reactions or blood clotting disorders, the vaccine very simply does not cause autism, nor is it associated with encephalitis or death. It does, however, protect against a potential devasting consequence of prior measles infection, subacute sclerosing panencephalitis (SSPE), which is an untreatable, relentlessly progressive neurologic disorder leading to death in about 1 in 10,000 individuals infected with measles. Undermining confidence in well-established vaccines that have met the high standards for quality, safety, and effectiveness that have been in place for decades at FDA is irresponsible, detrimental to public health, and a clear danger to our nation's health, safety. and security.

In the years following the pandemic, at the Center for Biologics Evaluation and Research we have applied the same unwavering commitment to public health priorities to the development of cell and gene therapies to address both hereditary and acquired rare diseases. During my tenure as Center Director we have approved 22 gene therapies, including the first gene therapy ever to be approved in the United States. However, we know that we must do better to expedite the development of treatments for those individual suffering from any one of the thousands of diseases potentially addressable by the advances in molecular medicine over the past decades. Drawing from learnings of the pandemic, the staff at the Center for Biologics Evaluation and Research are implementing best practices learned during the pandemic such as increased communication with product developers to further expedite bringing needed treatments to those in need. They have also been exploring the dramatic transformation of our regulatory approach to expedite the delivery of directly administered genome editing products. If thoughtfully approached and further developed and refined, these treatments have the potential to transform human health over the coming years.

Over the past 13 years I have done my best to ensure that we efficiently and effectively applied the best available science to benefit public health. As you are aware, I was willing to work to address the Secretary's concerns regarding vaccine safety and transparency by hearing from the public and implementing a variety of different public meetings and engagements with the National Academy of Sciences, Engineering, and Medicine. However, it has become clear that truth and transparency are not desired by the Secretary, but rather he wishes subservient confirmation of his misinformation and lies.

My hope is that during the coming years, the unprecedented assault on scientific truth that has adversely impacted public health in our nation comes to an end so that the citizens of our country can fully benefit from the breadth of advances in medical science. Though I will regret not being able to be part of future work at the FDA, I am truly grateful to have had the opportunity to work with such a remarkable group of individuals as the staff at FDA and will do my best to continue to advance public health in the future.

Sincerely,

Peter Marks

Peter Marks, MD, PhD