

February 5, 2021

The Honorable Xavier Becerra, Secretary of Health and Human Services-Designate
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Norris Cochran, Acting Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear HHS Secretary-Designate Becerra and Acting HHS Secretary Cochran:

We are writing as individuals who are leaders in our fields in medicine, public health, healthcare systems, and public policy, to express our strong support for Dr. Joshua M Sharfstein as Commissioner of the U.S. Food and Drug Administration (FDA). We have known Dr. Sharfstein for many years, some of us for decades, and can attest to his commitment to policies that are based on science and improve the health of all Americans. He also brings his integrity, leadership experience, his broad knowledge base, and his excellent working relationships with colleagues and leaders nationwide. When we learned in the media that he is being considered for Commissioner, we wanted to let you know why we think he is the best choice.

The FDA has been the gold standard as a regulator agency, and Dr. Sharfstein would strengthen that reputation as he addresses present and future challenges to balance needs of multiple constituencies, including the public health and the industries it regulates. As you know, scientifically questionable decisions regarding treatments such as opioids, hydroxychloroquine, Vioxx, and eteplirsen have contributed to the skyrocketing cost of medical care, and have made it difficult for patients and their physicians to make informed medical decisions. As one of the most important public health agencies in the world, it is essential that the FDA will have a strong and collaborative leader who knows the agency and will work well with other leaders within the U.S. Department of Health and Human Services, as well as with agencies throughout the country and the world.

Dr. Sharfstein has proven himself as a leader in numerous roles spanning many years: as the former Principal Deputy Commissioner of the FDA; in his roles as Secretary of Health for the state of Maryland and city of Baltimore; in his work in the U.S. Congress, and in his current role as Vice Dean for Public Health Practice and Community Engagement and Professor of the Practice at Johns Hopkins Bloomberg School of Public Health. At Johns Hopkins, he directs their recently created American Health Initiative, which trains professionals from all walks of life (such as police officers, clinic directors, doctors, lawyers, and teachers) to help improve health in their communities. Dr. Sharfstein knows the FDA and will ensure that its decision making is scientifically beyond reproach, transparent, and based on the principles of public health.

Dr. Sharfstein has a special ability to dissect complex problems, articulate core issues, and suggest pros and cons for his recommended course of action. Using a transparent, data-driven and evidence-based process, he put programs in place that improved the lives of all they served. All of these initiatives are well-documented in the major media as well as the most prestigious peer-reviewed journals. Since early in his career, Dr. Sharfstein has always been able to see the bigger picture and develop a plan, working collaboratively to solve problems. For example, during his Pediatric training in Massachusetts, he and his colleagues studied the impact of housing barriers on people's health, and attracted the enthusiastic involvement of then-Senator John Kerry, at a time before the impact of housing on health was considered a policy issue. He also became concerned about the boarding of children and adolescents with mental health problems in the Emergency Room for 24 -48 hours, because of lack of child mental health beds, and worked with other hospitals, state agencies, and the Massachusetts Governor's office to develop a plan to remediate the problem.

While not directly relevant to the role of the FDA Commissioner, these early examples illustrate that his excellent problem-solving and collaborative skills are inherent abilities that have enabled him to be particularly effective throughout his career. His work has also always been inclusive, gathering information from many perspectives and ensuring that the impact of his work reduced disparities due to poverty, race, ethnicity, and gender. He displayed these abilities in all of his prior positions, as illustrated by his election to the very prestigious National Academy of Science, Engineering, and Medicine, which recognizes individuals who have demonstrated outstanding professional achievement and commitment to service.

Clinical experience and scientific knowledge inform the work of the FDA; however, other expertise is also essential for Commissioners, and we are impressed with Dr. Sharfstein's ability to identify and communicate solutions to complex problems. He has shown these skills in his dealings with colleagues, a wide range of constituencies, and the general public. He has extensive knowledge and expertise in many of the issues of importance to the FDA, such as HIV/AIDS; tobacco; opiates; vaccines; cold medications; sunscreen; dietary supplements; infant formula; healthcare payment systems; and the need to resolve differences between those concerned about off label marketing and those focused on first amendment issues. His unquestioned integrity and his concerns about how financial conflicts of interest can influence health policies are clearly aligned with the Biden Administration.

Dr. Sharfstein is extremely well respected nationally and internationally, having lectured and published commentaries in prestigious medical journals on a wide range of topics relevant to the FDA, especially those focused on legislative and regulatory strategies to improve the health of all Americans. He has also published two books: *The Public Health Crisis Survival Guide: Leadership and Management in Trying Times* and *The Opioid Epidemic: What Everyone Needs to Know*.

This is the first time any of us have endorsed a candidate to be FDA Commissioner. The last several years have shown us how essential strong leadership from a public health perspective is for the FDA, and the costs to all Americans when that leadership is missing. Dr Sharfstein's extensive knowledge of the FDA and its broad mandate, his well-established integrity, and his broad-based experience of working collaboratively is needed to lead the FDA this year and in the future.

We are writing this letter because we value the importance of science to the future of our country and we understand how much is at stake. There is no doubt that Dr. Sharfstein has already established himself as a champion for evidence-based medicine and visionary leadership at the highest levels of government. He will bring great credit to the FDA as Commissioner.

Our names and affiliations (the latter for identification purposes only) are listed below. If you have any questions, please contact Dr. Barry Zuckerman at BarryZuckerman1@gmail.com.

Sincerely yours,

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