



August 31, 2020

Michael A. Carome, MD
Health Research Group
Public Citizen
mcarome@citizen.org

Dear Dr. Carome:

Thank you for your July 29, 2020 response to Stephen M. Hahn, MD, Commissioner of the Food and Drug Administration (FDA), and Jeff Shuren, MD, JD, Director of the Center for Devices and Radiological Health (CDRH). We appreciate you expressing your concerns to the FDA.

Your response raises a number of important issues. The agency takes clinical experience with medical devices very seriously. Patient safety is our foremost objective.

We would appreciate the opportunity to speak with you about your concerns. If you are interested and willing to speak with us, please contact me at William.Maisel@fda.hhs.gov or 301-796-5550 to arrange a call.

Sincerely,

William Maisel, MD, MPH
Director, Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration