

Division of Dockets Management  
Department of Health and Human Services  
Food and Drug Administration  
Commissioner Martin A. Makary M.D., M.P.H.  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

December 8, 2025

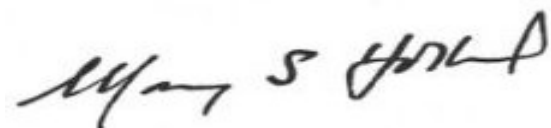
Dear Commissioner Martin A. Makary M.D., M.P.H.:

Enclosed is a Citizen Petition filed on behalf of Children's Health Defense by Mary S. Holland, Esq., Chief Executive Officer, Brian S. Hooker, Ph.D., Chief Scientific Officer, Kim Mack Rosenberg, General Counsel, and Ray L. Flores II, Senior Outside Counsel requesting that FDA revoke all licensure for COVID-19 mRNA vaccines as improperly granted.

This Citizen Petition incorporates results, findings, and conclusions gained by Alexandra (Sasha) Latypova, M.B.A., an independent writer and researcher on topics related to pandemic preparedness, EUA Countermeasures, and the PREP Act. Ms. Latypova is a pharmaceutical and medical device industry veteran with 25 years of experience across cardiovascular, oncology, immunology, CNS, infectious disease/HIV, musculoskeletal, and ophthalmic diseases. She co-led industry's largest validation study of AI-enabled analysis of electrocardiographic data collected in clinical trials. This effort resulted in the FDA revising its E14 Guidance for Industry, improving the precision and accuracy of cardiovascular safety studies, and introducing the first artificial intelligence-driven methods that maintain rigorous safety standards while reducing costs and risks to clinical trial subjects.

Mary S. Holland, Esq., and Brian S. Hooker, Ph.D., are available to answer questions and to provide any additional relevant information. We look forward to your timely review of this petition.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary S. Holland".

**Mary S. Holland, Esq.,  
Chief Executive Officer**

A handwritten signature in blue ink, appearing to read "Brian S. Hooker".

**Brian S. Hooker, Ph.D.,  
Chief Science Officer**

A handwritten signature in black ink, appearing to read "Kim Mack Rosenberg".

**Kim Mack Rosenberg,  
CHD General Counsel**

A handwritten signature in blue ink, appearing to read "Ray L. Flores II".

**Ray L. Flores II,  
Senior Outside Counsel**

cc:  
Sasha Latypova