U.S. FOOD & DRUG ADMINISTRATION

November 16, 2018

Michael A. Carome, M.D.
Health Research Group
Public Citizen
1600 20th Street, NW
Washington DC 20009

Dear Dr. Carome:

Thank you for contacting the Food and Drug Administration (FDA) Commissioner, Scott Gottlieb, M.D., on behalf of Public Citizen's Health Research Group. We acknowledge receipt of your letter dated October 29, 2018, which is a follow-up to your letters dated July 25 and 30, 2018, concerning the conduct of certain clinical trials involving the drug ketamine conducted by investigators at the Hennepin County Medical Center (HCMC).

Your most recent letter discusses the Form FDA 483 (Inspectional Observations) for the FDA's August 2018 inspection of the HCMC's Institutional Review Board, Human Subjects Research Committee. Because this inspection is an open compliance matter, we are unable to share additional information at this time.

We acknowledge your concerns for the rights, safety, and welfare of human subjects. The FDA takes seriously reports of possible violations of the laws in place to protect human subjects and will take action where warranted.

You may request further information about this matter under the Freedom of Information Act. Freedom of Information requests can be made in writing or online. Written requests should be mailed to the following address: Food and Drug Administration, Division of Freedom of Information, Office of the Executive Secretariat, OC, 5630 Fishers Lane, Room 1035, Rockville, MD 20857. If you wish to submit your request online, please refer to the following website: http://www.accessdata.fda.gov/scripts/foi/FOIRequest/index.cfm. Please note that federal law protections for confidential information may limit the agency's ability to respond to requests, particularly while investigations are ongoing.

Sincerely,

David Burrow -S Digitally signed by David Burrow -S
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