



August 3, 2018

Michael A. Carome, M.D.
Public Citizen's Health Research Group
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 the Public Citizen's Health Research Group. We acknowledge receipt of your original letter dated July 25, 2018, and follow-up letter dated July 30, 2018.

We understand that you have concerns about the conduct and oversight of two prospective clinical trials that allegedly involved comparing the safety and effectiveness of ketamine with those of other drugs for management of agitation without consent of the subjects. We appreciate your efforts in bringing this matter to our attention, and we assure you that it will receive prompt and appropriate consideration.

While we generally do not comment on specific clinical trials, the FDA is committed to maintaining high science-based standards and takes seriously the quality and integrity of clinical research. 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 from the Freedom of Information Office. 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 -

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David Burrow, Pharm.D., J.D.

Director

Office of Scientific Investigations

Office of Compliance

Center for Drug Evaluation and Research

Food and Drug Administration

Digitally signed by David Burrow -S
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