From:	Menikoff, Jerry (HHS/OASH)
To:	Michael Carome; Woodcock, Janet (FDA/OC); Giroir, Brett (FDA)
Cc:	Levine, Rachel (HHS/OASH); Seshasai, Karuna (HHS/IOS); Robinson, Wilma (HHS/IOS); Buchanan, Lisa (HHS/OASH)
Subject:	RE: Complaint letter about an unethical NIH-funded clinical trial involving patients with status epilepticus
Date:	Tuesday, June 8, 2021 9:28:51 AM

Dear Dr. Carome,

Thank you for contacting the Office for Human Research Protections (OHRP).

OHRP has responsibility for oversight of compliance with the U.S. Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46, found at www.hhs.gov/ohrp/regulations-and-policy/guidance). In carrying out this responsibility, OHRP reviews allegations of noncompliance involving human subject research conducted or supported by HHS or that are otherwise subject to these regulations, and determines whether to conduct a compliance evaluation.

OHRP will review the information provided in your email, and will contact you if additional information is needed or if we are unable to pursue your concerns. Do not hesitate to contact us to provide additional information if more becomes available or if you have any questions.

Sincerely,

Jerry Menikoff
Director
Office for Human Research Protections

Email: jerry.menikoff@hhs.gov
Office: (240) 453-6900
www.hhs.gov/ohrp

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From: Michael Carome <mcarome@citizen.org>
Sent: Tuesday, June 08, 2021 6:56 AM
To: Menikoff, Jerry (HHS/OASH) <Jerry.Menikoff@hhs.gov>; Woodcock, Janet (FDA/OC) <Janet.Woodcock@fda.hhs.gov>; Giroir, Brett (FDA) <CommissionerFDA@fda.hhs.gov>
Cc: Levine, Rachel (HHS/OASH) <Rachel.Levine@hhs.gov>; Seshasai, Karuna (HHS/IOS) <Karuna.Seshasai@hhs.gov>; Robinson, Wilma (HHS/IOS) <Wilma.Robinson@hhs.gov>; Buchanan, Lisa (HHS/OASH) <Lisa.Buchanan@hhs.gov>
Subject: Complaint letter about an unethical NIH-funded clinical trial involving patients with status epilepticus

Dear Dr. Menikoff and Dr. Woodcock:

Please see the attached letter from Public Citizen requesting that the Office for Human Research Protections and the Food and Drug Administration (FDA) immediately launch compliance oversight investigations into the already-completed National Institutes of Health-funded Established Status Epilepticus Treatment Trial (ESETT) and its review and approval by the responsible institutional review board(s) (IRBs). Based on our review of the protocol and relevant background scientific literature, we are concerned that the trial, as proposed and conducted, failed to (1) materially comply with key requirements of Department of Health and Human Services and FDA regulations for the protection of human subjects at 45 C.F.R. Part 46 and 21 C.F.R. Parts 50 and 56, respectively, and (2) satisfy the basic ethical principles upon which those regulations are founded. Hard copies of the letter will follow by regular mail.

Please note that we would be happy to provide upon request copies of all documents cited in our letter.

Please contact me if you have any questions or need additional information.

Sincerely,

Michael A. Carome, M.D.
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