DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

November 17, 2021

Michael A. Carome, M.D., Director
Public Citizen's Health Research Group
1600 20th Street, N.W.
Washington, DC 20009

Sent via email to: mcarome@citizen.org

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug take the following three actions:

1) Promptly initiate clinical-investigator disqualification proceedings against Dr. Jon B. Cole, Dr. Lauren R. Klein, and their co-clinical investigators for repeatedly and deliberately initiating and conducting clinical investigations of investigational drug products subject to section 505 of the FDCA without submitting or having in effect FDA-required INDs.

2) Initiate disqualification proceedings against the institutional review board (IRB) (named the "Human Subjects Research Committee") at Hennepin County Medical Center/Hennepin Healthcare (HCMC) in Minneapolis, MN, for repeatedly failing to comply with the agency's regulations at 21 C.F.R. Part 50 (Protection of Human Subjects) and Part 56 (Institutional Review Boards) — noncompliance that adversely affected the rights and welfare of the vulnerable human subjects unwittingly enrolled in the clinical investigations conducted by Dr. Cole and Dr. Klein in violation of the FDA's IND requirements. This noncompliance was documented in the Form FDA 483, Inspectional Observations (483-Form) pursuant to the FDA's August 7-23, 2018, inspection of the HCMC IRB.

3) Require HCMC to develop and implement a plan for contacting the more than 1,700 human subjects (or the closest surviving family members of deceased subjects) who were unwittingly enrolled in the clinical investigations conducted by Dr. Cole and Dr. Klein without the subjects' legally effective informed consent and informing of them of (a) the serious regulatory violations documented by the FDA during its inspections of HCMC IRB and clinical investigator records related to those clinical investigations; and (b) the fact that the clinical investigators violated the subjects' rights and endangered the health and welfare of some subjects.

This petition was received and processed under CFR 10.30 by this office on 11/17/2021 and it was assigned docket number FDA-2021-P-1227. Please refer to this docket number in future correspondence on this subject with the Agency.

Also, note that the acceptance of the petition for filing is a procedural matter and in no way reflects the agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2021.11.17 15:15:20 -05'00'

Karen Malvin
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)