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April 28, 2022

Re: Docket No. FDA-2021-P-1227

Dear Dr. Carome and Dr. Wolfe:

This letter responds to your citizen petition, which was received by the Food and Drug Administration (FDA or Agency) on November 17, 2021 (Petition). The Petition requests "stronger compliance actions" following FDA's publication on its website on October 19, 2021, of two Warning Letters to Dr. Jon B. Cole (dated May 5, 2021) and Dr. Lauren R. Klein (dated May 6, 2021), respectively, relating to clinical investigations conducted at the Hennepin County Medical Center (HCMC) in violation of applicable Agency regulations. Specifically, the Petition requests that FDA:

- 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 Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 355) without submitting or having in effect FDA-required investigational new drug applications (INDs).

- Promptly initiate disqualification proceedings against the HCMC Institutional Review Board (IRB) for repeatedly failing to comply with the agency's regulations at 21 C.F.R. Parts 50 and 56.

- Promptly 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.

(Petition at 2-3).

FDA has carefully considered your Petition and the comments submitted to the docket and acknowledges the importance of the issues they raise. As with judicial enforcement, the Agency makes decisions regarding whether to pursue administrative enforcement action, including disqualification proceedings, on a case-by-case basis, considering all relevant facts and circumstances. Where appropriate, the Agency considers information provided by the individuals or entities involved, as well as other information regarding the specific circumstances of the matter. At this time, we are not taking the actions you requested. Therefore, in accordance with § 10.30(e), your Petition is denied. However, we intend to continue to consider all the options available to the Agency as we determine whether to pursue additional compliance actions related to this matter.

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
Date: 2022.04.27 13:59:23 -04'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research