

## Catherine Cline

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**From:** Elizabeth Brehm  
**Sent:** Tuesday, June 14, 2022 10:18 PM  
**To:** VRBPAC@fda.hhs.gov; CBERVRBPAC@fda.hhs.gov  
**Cc:** Aaron Siri; Catherine Cline  
**Subject:** Waiver of Dr. Hildreth  
**Attachments:** VRBPAC-06.14.22-06.15.22-Meeting-James-Hildreth-Waiver-to-Allow-Participation.pdf;  
VRBPAC-06.14.22-06.15.22-Meeting-James-Hildreth-Acknowledgment-of-Financial-Interest\_0.pdf

Dear Dr. Atreya and Members of VRBPAC,

We write on behalf of our client, Informed Consent Action Network, concerning Dr. Hildreth and his status as a temporary voting member of VRBPAC. As shown in his Acknowledgement of Financial Interest form (attached), Dr. Hildreth has both personal financial interests and financial interests of his employer which can be affected by the particular matter currently before VRBPAC, both today and tomorrow, and potentially at later dates as well. Dr. Hildreth's College is a site for a Covid-19 vaccine trial and is due to receive between \$1.5 – 2 million dollars for conducting the trial. His college has also enrolled participants in the very trials being considered by VRBPAC – Moderna's pediatric Covid-19 trials – for which his college will receive approximately half a million dollars. Additionally, Dr. Hildreth will personally make up to \$5,000 for enrolling participants in one of these trials.

Despite the claim that "it would be extremely difficult and unlikely within the limited time allotted to find an equally accomplished individual to replace Dr. Hildreth," this is precisely what VRBPAC must do in order to maintain a committee free from conflict. Surely, the FDA and VRBPAC knew months ahead of time that Moderna Covid-19 vaccine trials were to be discussed at VRBPAC and had time to find voting members who did not stand to gain financially from those products.

It is clearly not appropriate to proceed with this voting member, regardless of his experience and expertise (as described in the attached Waiver), and we urge you to discount his vote from today's meeting and bar him from participating and voting at tomorrow's meeting, which will also consider yet another Moderna pediatric Covid-19 vaccine, and from participating and voting at any future meetings where a Covid-19 vaccine is the matter at issue.

Regards,  
Elizabeth

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