May 3, 2023

Honorable Chairman, Congressman James Comer
House Oversight & Accountability Committee
2157 Rayburn House Office Building
Washington, D.C. 20515-6143

RE: Letter of Inquiry: Committee on Oversight & Accountability

Dear Honorable Chairman, Congressman James Comer,

Thank you for your leadership on the Oversight & Accountability Committee. We are reaching out with a formal letter of inquiry regarding the federally funded programs related to public health and its associated clinical research. CIAAG is a national nonprofit organization dedicated to the convergence of public-health and individual rights. As a part of our work, we analyze the public health policies and strategies from the Administration and the federal agencies with the aim to identify areas that conflict with civil liberties and the free market.

We are writing today in regards to the NIH-HEAL Initiative. We have a number of concerns regarding the structure of the clinical research projects being funded under this program, the safety of the research participants and integrity in the data collection process.

Our research has shown that numerous federally funded research projects at NIH and its associated sub-agencies and programs are being operated without obtaining the patient's informed consent. While data collection via Electronic Medical Record is common practice, these new high risk projects are permitting patient private care to be changed on the front-end in order to facilitate the desired research. In practice, patients are being put into different treatment programs under the impression that these programs are properly studied for their safety and efficacy. When in reality, they are being placed into randomized clinical trials without their knowledge or informed consent.

As such, we are asking the Committee of Oversight & Accountability to send a formal inquiry to National Institutes of Health, NIH-HEAL Initiative, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Institute on Drug Abuse (NIDA) regarding the Hemodialysis Opioid Prescription Effort (HOPE) Program.(1)

HOPE Program Overview:

> *"Pain is a common problem in Medicare end-stage renal disease (ESRD) hemodialysis patients. The rate of chronic opioid prescriptions in ESRD hemodialysis patients, approximately 20 percent, is higher than the rate in Medicare comparison populations.*

(1) *Integrated Approach to Pain in Hemodialysis Patients | NIH HEAL Initiative*. (2023, February 27). NIH HEAL Initiative. Retrieved May 1, 2023, from https://heal.nih.gov/research/clinical-research/hemodialysis

> ***ESRD hemodialysis patients are an ideal population in which to launch and monitor interventions because of their long-term participation in monitored treatment and the availability of data resources.*** *To date, many interventions, both behavioral and medical, have not been tried in this population or have not been rigorously evaluated by randomized controlled trials. These interventions could reduce the rate of opioid prescription and opioid use and could address related issues, such as depression, anxiety, and pain."*

The HOPE Program Overview states that ***"many interventions, both behavioral and medical, have not been tried in this population or have not been rigorously evaluated by randomized controlled trials."*** This statement makes it clear there is *limited or no evidence* to support the safety or efficacy of the proposed treatments. Patient care should never be implemented into the private healthcare system until it has been properly studied via controlled clinical trials and independently verified. The HEAL-Initiative deploys a new approach using decentralized clinical trials run through the Electronic Medical Records. This poses concerns regarding individuals rights, informed consent, and patient safety.

About the Program

> "The Hemodialysis Opioid Prescription Effort (HOPE) consortium will develop an intervention to address the problems of pain and opioid use in U.S. hemodialysis populations.
>
> The consortium will initiate multipronged pain treatment tailored to each patient, without opioids, and using buprenorphine and other novel agents to reduce dependence on opioids in affected patients."

The consortium will be researching patients with end-stage renal disease to determine if they can be treated via alternative/complementary approaches or through the use of buprenorphine rather than with standard mu-antagonist analgesics.

Questions 1 - 7:

1. How are the patients being selected for the trial?
2. Are the patients' providers aware their patient is enrolled in the trial?
3. Are these patients given knowledge that they are being provided care that has not been properly vetted for its safety or efficacy yet?
4. Do the patients provide explicit informed consent?
5. Are the patients compensated?
6. Are there controls in place to ensure patients can "drop out" should the recommended modality be ineffective? Or, are they unable to do so because they are under the impression there are no alternative options and the care they are receiving is deemed "best-practice"?
7. How are the patient insights being captured?

> *"Analyses will consider comorbid illnesses, such as diabetes and mental health disorders, and social determinants of health, such as socioeconomic status, social isolation, social support, residential factors, and perception of racial discrimination. The goal is to identify novel risk factors for pain and opioid use in this population."*

Question 8: Please elaborate on the study goals and how the social determinants of health (SDOH) would provide insight into pain and opioid use in this population. While the SDOH may provide insight into other areas about this population, this study appears to be seeking to create a connection with the SDOH to pain and opioid use in a population with end-stage renal disease, a known painful condition.

> "End points will be chronic opioid prescription rates, prescription drug doses, pain control, patient satisfaction with care, perception of quality of life, hospitalization rates, and mortality rates**."**

Question 9: Since an opioid sparing/avoidance approach is being taken by the study, how do you justify the use of opioid prescribing rates as a reliable data point to determine the study's outcome?

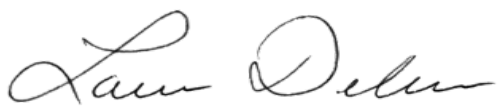
> *"The consortium may use electronic health records to capture real-time risk factor and outcomes data by leveraging and expanding a pilot set of more than 200 standardized data elements that the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Chronic Kidney Disease eCare Plan Working Group identified and prioritized for comprehensive chronic kidney disease care."*

Question 10: How is patient confidentiality and privacy being safe-guarded?

While this correspondence is limited in its scope to the HOPE Program, the issues being brought forth to the House Oversight & Accountability Committee are far reaching and go beyond this single project. The HOPE Program is merely an example of a much larger, systemic issue taking place with the convergence of public-health initiatives and their impact on private healthcare systems, and ultimately the public-health policies, and subsequent additional funding opportunities being derived from this work.

Thank you for your leadership and taking action on this important matter.

Sincerely,



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