May 21, 2023

Office of the United Nations High Commissioner for Human Rights

CH-1201 Geneva, Switzerland

## RE: Human rights challenges in addressing and countering all aspects of the world drug problem

Dear High Commissioner Turk,

Thank you for the opportunity to contribute to the OHCHR report and upcoming panel discussion on human rights challenges in addressing the world drug problem. CIAAG is a national nonprofit organization focused on the convergence of public-health policy and individual rights in the healthcare and drug policy arena.

**Background:**

The United States created a number of federal strategies aimed at addressing drug abuse in the nation, primarily focused on decreasing illicit use by reducing medicinal access to opioid analgesics. The idea being that a reduction in the medical supply of opioids would result in a decrease of illicit use and its associated costs. However, it was recognized that a plan would need to be devised to treat pain as it was still a highly prevalent health issue in the nation and many would be affected if the supply to opioid analgesics was restricted.

As such, the U.S. Government created public, private-partnership (P3) initiatives with various stakeholders including, but not limited to: academia, national and international government agencies, industry, professional societies, patient advocacy groups, foundations and philanthropic organizations.

CIAAG’s analysis of the work conducted by various stakeholders uncovered serious acts of corruption, coordinated disinformation campaigns, violations of human rights (including lack of informed consent in human clinical trials), interference with the healthcare marketplace and the creation of a de facto monopoly that operates outside the public’s view.

**Issues:**

The work of the public, private-partnership is conducted without the public’s knowledge. Pain advocacy organizations directly contracted to perform this work have historically denied their participation to the public. Industry stakeholders working in private coalitions now resemble public relations firms; they send coordinated messages (often devoid of facts) to various representative populations misframing what is actually taking place within the public health policy arena to promote and draw public favor for the national strategies of the federal government.

These entities that were entrusted to protect the interests of the public have done a great disservice to those they were intended to serve (which largely consist of disabled, elderly and other vulnerable populations). A concentrated effort currently exists that prevents individuals in need of opioid based medications from actively participating in (and in some cases even being aware of) drug and healthcare policy discussions despite national guidance documents advising that all interested parties have the opportunity to participate.

The pain advocacy organizations engaged in the public, private-partnerships are no longer advocating to protect rational access to opioid based pain medications and instead, have focused their efforts towards promoting opioid-sparing policies across the nation. These same entities have publicly stated they support access to opioids but their actual organizational efforts are focused on encouraging patients to engage in research activities that support the use of complementary care treatments to replace opioid medications. This is highly unethical and fraudulent activity. By not conveying their true mission to the public while withholding material facts, these entities are engaged in exploitation of the patient population they profess to serve.

Pain advocacy organizations along with numerous other stakeholders are contracted to help implement federal strategies and influence their prospective patient population(s) to *“accept these changes in access to pain care in the nation.”* They have abandoned the cause of protecting rational access to opioid analgesics in favor of lucrative grants to implement the new model of care *despite the lack of evidence to support this shift in care*. These entities are intimately aware that the modalities they are promoting to the public are replacements for opioid based medications and that patients are actively being studied by clinical researchers at various academic institutions to determine what the benefit of these various treatments may or may not be. These are acts of collusion that cannot be overlooked. These entities are working together without transparency to the public and are systematically changing public and individual health policy based on theories and agendas. They are using the live patient population to garner data on modalities that have shown to be ineffective in previous studies and appear to be cherry-picking from large data sets in order to support predetermined outcomes that declare the modalities to be a sufficient replacement for pharmacological treatments.

**Structure:**

In order for this to take place, pragmatic clinical trials have been embedded into the private healthcare and Veterans Administration’s (VA) delivery health systems. Meanwhile, patients with painful illnesses and conditions are denied access to opioid based pain medications and forced to choose between non-pharmacological treatments or non-opioid based medications to manage their pain.

Unfortunately, (as previously indicated) many of these treatment modalities *have not been proven safe or effective,* leaving the patient suffering for the sake of clinical data to be collected through the electronic medical record. The severity of these actions cannot be understated. Our national leaders have permitted the implementation of these healthcare practice changes within the private medical encounter prior to having these treatments proven for their safety and efficacy, citing lack of patient participation and willingness to consent, as a justification for the need to embed these clinical trials into the healthcare system. This was achieved without patient or physician knowledge,effectively circumventing consent and obtaining the desired research by force. Patients do not have the ability to drop out of these studies, as they are not even aware they are partaking in them.

Federal agencies and private enterprises have worked together to change rules and regulations to make this work; it is technically legal on paper, but in its application, this work violates international code of human rights and the Belmont Agreement for human research studies.

CIAAG participated as a subject matter expert for the United Nations Office of Drugs and Crime for the creation of a [Digital Roadmap](https://www.unodc.org/documents/donors/PPPfactsheet-Supplydemand-reduction-WEB.pdf) (1) on the use of Public-Private-Partnerships. The committee agreed that *“oversight must ensure that evidence-based best practices are developed based on rigorous science and informed consent,* ***with no corners cut****.”* This recent statement along with the Human Rights Resolution 54/22, affirm the United Nations and the Office of Human Rights Council commitment to the preservation of human rights in the face of the world drug problem.

A review of the prevention strategies currently undertaken by the U.S. government reveals a coordinated effort being undertaken through the public,private-partnership mechanism to circumvent basic components of informed consent in order to fast track research. This process has been proven to not be without its risks as patients have incurred both bodily injury and psychological distress as a result.

I ask the OHCHR to please refer to the attached 2022 CDC Opioid Prescribing Guidelines Draft Report as an example of how national medical guidelines are being issued that align with the very same items identified as “needing research.”

The authors of the 2022 CDC Opioid Prescribing Guidelines (Draft Version) repeatedly outline ***the lack of data to support alternative therapies***. Yet, despite this open acknowledgement, they proceed to create a national recommendation for these same modalities *to become the first line of therapy* for patients in the clinic. CIAAG provided a [detailed analysis](https://uploads.documents.cimpress.io/v1/uploads/71da9192-6384-421c-ab4b-416014339c7a~110/original?tenant=vbu-digital) (2) of the 2022 Opioid Prescribing Guidelines Draft Report outlining the serious conflicts within the report along with concerns of committee member bias, data integrity issues and areas lacking transparency.

Comparing the the [2019 Pain Management Task Force Repor](https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf)t(3) to the 2022 CDC’s Opioid Prescribing Guidelines (Draft Version attached), it is clearly seen that the task force report recommendations for “desired research” are the very same recommendations the 2022 CDC Opioid Prescribing Guidelines are now recommending to be implemented as “best-practices” in the private patient clinic.

The totality of the changes has effectively turned the patient private clinic into a quasi-laboratory for academia to use as an opportunity to fill research gaps and explore new research opportunities. CIAAG’s exclusive report, [Violation of a Nation](https://uploads.documents.cimpress.io/v1/uploads/4d35405a-6dff-406b-a680-008147ce2218~110/original?tenant=vbu-digital)(4), identified this issue back in 2019 and explores the historical background that led us to the current national strategies. Additionally, refer to the report, [A Crisis Exploited](https://uploads.documents.cimpress.io/v1/uploads/74d840cb-f00d-41ab-9157-27329ace4191~110/original?tenant=vbu-digital)(5), which explores various stakeholders conflicts of interests and activity.

In order to permit this work to take place, the U.S. government has taken a number of steps to change the rules and regulations surrounding how clinical trials are conducted. One of the most notable changes was the issuance of a Waiver or Alteration of Informed Consent in Human Clinical Trials in 2017. (This change was made without notification for public input).

A review of the work being undertaken by the U.S. federal agencies and their associated partners reveals the vigorous effort towards the integrating human clinical trials research into the private healthcare system. Stakeholders involved in these efforts contend that “obtaining informed consent is not practical “and cite a lack of patient “buy-in” as an obstacle to the research. This is a clear admittance of the stakeholder’s knowledge that, if afforded a choice, many patients would not participate in these research projects. In response to this knowledge, a system was created that circumvented the need to obtain informed consent to obtain the necessary data.

The impact of these actions cannot be understated. Private medical care has been changed ***on the front-end*** in order to permit clinical research to be conducted via the electronic medical records.

While the agencies and entities engaged in this work defend its use under the guise that it is “minimal risk”, the data does not support this. Since the issuance of these policies, the U.S. has seen increases in suicides and overdoses. In order to effectively address the international issue of drug abuse, we must come together to create solutions that work for all of us. The current system excludes representation from any organization that advocates for the medicinal use of opioid analgesics. There are concerns about data integrity, misinformation/disinformation campaigns coming from various stakeholders and violations of human rights.

We thank the OHCHR for considering our concerns in the upcoming report and panel discussion on human rights challenges in addressing the world drug problem.

Thank you,

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**Citations**

1. *The path forward for effective public-private partnerships in drug control: Drug supply and demand reduction*. (2022). UNODC. Retrieved May 21, 2023, from <https://www.unodc.org/documents/donors/PPPfactsheet-Supplydemand-reduction-WEB.pdf>

1. Deluca, L., & Harner, S. R. (2022) *CDC Opioid Prescribing Guidelines Draft A CIAAG Analysis*. Retrieved May 21, 2023, from <https://uploads.documents.cimpress.io/v1/uploads/71da9192-6384-421c-ab4b-416014339c7a~110/original?tenant=vbu-digital>

1. *Pain Management Best Practices Inter-Agency Task Force Report*. (2019). hhs.gov. Retrieved May 21, 2023, from <https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf>

1. Deluca, L., & Harner, S. R. (2019, April 15). *Violation of a Nation*. www.ciaag.net. Retrieved August 23, 2020, from <http://uploads.documents.cimpress.io/v1/uploads/c7c18e1c-2c3d-4ffd-b251-2ddba53a2d8b~110/original?tenant=vbu-digital>

1. Deluca, L., & Harner, S. H. (2020). *A Crisis Exploited*. Retrieved May 21, 2023, from <https://uploads.documents.cimpress.io/v1/uploads/74d840cb-f00d-41ab-9157-27329ace4191~110/original?tenant=vbu-digital>