TITLE: Accessing the Impact of Public, Private-Partnerships and Drug Control

Over the past decade, the United States created a number of federal strategies aimed at addressing drug abuse in the nation. The goal was to decrease illicit drug abuse through reducing the medical use of opioid analgesics. It was theorized that a reduction in the availability and use of pharmaceutical grade opioids would result in a decrease of illicit misuse and its associated costs. With pain being such a prevalent, and costly health issue in the nation, it was anticipated that many who use opioid analgesics would be affected if the supply was restricted; therefore, a plan to treat pain was needed to accompany this desired, strategic shift.

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:

While the ideas stemming from the national strategic work are intended to improve patient care and outcomes, this is not what is seen in the results since its application. Since the implementation of the opioid sparing policies, patient satisfaction has markedly deceased with many patients reporting experiences of abrupt discontinuation of their previously stable

medication regimens. These patients are experiencing declining physical and mental health and are at increased risk of suicide.

How did we get so far off the mark and how do we get back on track? We need to take a closer look as to why we are seeing these negative outcomes.

One of the primary issues resulting in this disconnect is the lack of transparency and oversight of the stakeholders' work conducted within the public, private-partnerships. The public is often unaware of this work as it is outside their purview. Pain advocacy organizations, academia, media outlets and lawmakers are working together, implementing the national strategic goals through private channels. The public, private-partners engage in undisclosed committee work and when asked, have historically denied their participation. There are no requirements for the public, private-partners to maintain public transparency; nor are there requirements for them to report their goals and/or outcomes of their work. Industry stakeholders working in private coalitions now resemble public relations firms; sending coordinated messages (often devoid of facts) to various representative populations, mis-framing 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 acts are in direct opposition to the stated directives in federal guidance documents. The National Prevention Strategy (1), the National Pain Strategy (2), the Federal Pain Research Strategy (3), and other federal guidance reports explicitly discuss the importance of partnering with the patient community in all areas of this work. However, what we see is an exclusionary

process taking place. Academic institutions and pain advocacy organizations are working together to promote and implement the nation's goals of "changing the perception of how pain is treated and managed" while omitting relevant scientific evidence and neglecting to represent the patients' interests. Relevant scientific evidence is omitted in an effort to discredit the medical use of opioid analgesics in favor of promoting a self-management model of care as the primary mode of treatment for all illnesses and conditions.

This is in direct opposition to what we should be seeing. Instead of having pain advocacy organizations advocate for rational access to opioid-based medications for their respective communities, they are assisting the implementation of the governmental goal to have this medication restricted and replaced by ineffective (and often unproven) treatment modalities. The entities entrusted to protect the interests of the public have done a great disservice to those they were intended to serve (which largely consists of disabled, elderly and other vulnerable populations). The current approach and structure of the public, private-partnership initiatives prevent individuals in need of opioid based medications and the organizations that represent their interests, from actively participating in (and in some cases, even being aware of) relevant 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. Instead, their efforts are focused towards promoting opioid-sparing policies across the nation. These same entities publicly proclaim they support access to opioids; however, observation of their actions reveals

their true intent. Their organizational efforts are focused on encouraging patient engagement in research activities designed to study the efficacy of complementary and alternative care treatments designed to replace opioid medications. This is highly unethical and fraudulent activity. These entities are failing to convey their intent and true mission to the public; therefore, engaging in the exploitation of the patient population they profess to serve.

Pain advocacy organizations along with numerous other stakeholders are contracted to help implement federal strategies while influencing 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 a new care model *despite the lack of evidence to support this shift*. These entities are intimately aware that the modalities they are promoting to the public are intended replacements for opioid based medications. They are also aware that clinical researchers from various academic institutions are actively studying the patient population to determine if the offered treatments provide any benefit. These are acts of collusion that cannot be overlooked. A structural review of this work reveals a group of industry stakeholders working together privately, without transparency to the public in order to systematically change public and individual health policy based on theories and agendas.

The increased use of decentralized, pragmatic clinical trials in the "real-world" setting has turned the patient medical encounter into an opportunity for researchers to explore their theories without needing to obtain the participants' informed-consent. By embedding clinical trials into the private healthcare system, clinical researchers are able to perform studies they were previously

unable to conduct. Instead of accessing existing patient data to analyze the pros and cons of current modalities to develop best-practices, the patient population is restricted from accessing opioid-analgesics which forces their engagement in the desired modalities/studies, (as that is all that is available). The patient will then participate (without their knowledge or consent) and research is developed from their documented experience, found in the electronic medical record. Previous studies have already shown that many of these modalities (that patients are now required to utilize) are ineffective for the treatment of illness/pain. It appears this is being done to permit cherry-picking from large data sets to manufacture the necessary evidence to satisfy a desired, predetermined outcome; to show these modalities are a sufficient replacement for pharmacological treatments.

Structure:

By embedding pragmatic clinical trials in the delivery of care systems for both private and Veterans Administration's (VA) beneficiaries, our nation can simultaneously fund and pursue previously unattainable research projects. This new system permits patients with painful illnesses and conditions to be denied access to opioid based pain medications; they are forced to choose between non-pharmacological treatments or non-opioid based medications to manage their pain, regardless of their known ineffectiveness. The primary goal is to get as many patients off of opioid-based medications as possible, even when the discontinuation of this vital medication causes a decline in the patient's mental and physical health. This aforementioned scenario has become increasingly common since the inception of opioid-sparing policies in the

nation. Despite this, we have seen no desire to examine or funding directed to quantify these resulting negative outcomes.

Patients who previously utilized opioid analgesics to manage pain are now forced into a type of step-therapy; a lengthy process of trying and failing different modalities in an attempt to manage their painful symptoms. Unfortunately, (as previously indicated) many of these treatment modalities *have not been proven safe or effective,* leaving the patient suffering in favor of collecting clinical data through the electronic medical record. Oftentimes, the opportunity to receive access to opioid analgesics is no longer an option regardless of whether or not the patient has already tried and failed existing alternative/complementary therapies.

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 safe and effective, citing lack of patient participation and willingness to consent as justification for the need to embed these clinical trials into the healthcare system. This is achieved without patient or physician knowledge, effectively circumventing consent and obtaining the desired research by force. Patients are unaware they are enrolled in these studies; therefore, they are unable to select out.

Federal agencies and private enterprises have worked together to make this work technically legal by changing rules and regulations. This work violates the International Code of Human Rights and the Belmont Agreement for Human Research Subjects (4).

This issue of using private citizens without their informed consent reached the international stage at the United Nations Office of Drugs & Crime. In 2021, CIAAG's Executive Director, Lauren Deluca, was selected as a subject matter expert for the United Nations Office of Drugs and Crime to help develop an international guidance document on the use of public, private-partnerships and the recommendations/best-practices for nations to integrate and use.

CIAAG's concerns regarding the circumvention of informed consent in the United States was taken into consideration and integrated into the final guidance document, the UNODC's Digital Roadmap for Effective Public, Private-Partnerships in Drug Control (5). The final guidance states 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, reaffirm the United Nations and the Office of Human Rights Council's commitment to the preservation of human rights.

The initial federal guidance reports outlined a collaborative effort to include all stakeholders. The creation of precision medicine objectives was designed to benefit all patients with an aim to reduce stigma while improving public-health outcomes; it is clear that efforts to accomplish these objectives have failed. Year after year, patient suicides and national overdoses have drastically increased since the inception of the nation's opioid-sparing polices. A review of the U.S. government's prevention strategies reveals a coordinated effort utilizing the public, private-partnership mechanism to circumvent basic components of informed consent in order to fast track research; changing rules and regulations to financially benefit the various stakeholders involved in the public, private-partnership initiatives.

Pain advocacy organizations (working in the drug control arena) participating in the public, private-partnership initiatives, curate and coordinate a public-narrative to garner support for the national strategic goals while presenting themselves to the public as independent advocacy organizations. Their websites are often devoid of examples of advocacy activities they engage in, committee work they have participated in, or what their specific tangible goals are as an organization leaving their members unaware of what their actual mission and goals are. Through the use of semantics and euphemisms, these organizations avoid any public discourse that would reveal their true organizational focus. Their online platforms have been weaponized; they spread misinformation manufactured to confuse and pacify the individuals they profess to serve. This is done by design; these organizations recognize they would lose public support if they were forthcoming with the organizational changes, they have adopted over the past several years. Their messaging has turned into a public-relations campaign to implement national strategic goals to their respective communities and to report back to the collaborative any "issues" they are encountering in the process. These are industry actors; working in a closed circle, locking out the people they were assembled to represent. Instead, they are working to herd their respective communities into participating in the needed clinical research that supports the removal of opioid based medications for people with serious illnesses, disease and incurable conditions.

The organizational stakeholders of the public, private-partnership initiatives are often selected to represent the patient community on state/federal opioid task forces and committees. These committees are convened to advise and oversee changes in medical guidance for the treatment of disease/illness based on systematic-evidence reviews. The resulting recommendations of these

committees frequently contain stigmatic language and bias against the utilization of opioid based medications. However, a close review of these recommendations reveal they are not based on the scientific data found in the systematic-evidence reviews (provided by AHRQ), but rather are constructed to align with federal reports seeking additional research on various modalities to potentially treat pain.

The issuance of the 2022 CDC Opioid Prescribing Guidelines Draft Report demonstrates how national medical guidelines are issued that align with the same items identified as "needing research" by other federal committees and agencies.

A review of the 2022 CDC Opioid Prescribing Guidelines (Draft Version) reveals the authors of the report repeatedly state there is a ***lack of data to support the use of alternative therapies***. Yet, despite this open acknowledgement, the authors proceed to create national recommendations for these same modalities *to become the first line of therapy* for patients in the clinical setting. CIAAG provided a detailed analysis (6) 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 other areas lacking transparency.

In comparing the 2019 Health and Human Services Pain Management Task Force Report (7) to the 2022 CDC's Opioid Prescribing Guidelines (Draft Version), 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" that will be offered to the patient as a treatment option during the clinic visit.

The totality of these changes has effectively turned the patient private clinic into a quasi-laboratory for academia and other interested stakeholders, to use as an opportunity to fill research gaps and explore new research opportunities. CIAAG's exclusive report, Violation of A Nation (8), identified this issue back in 2019; we explored the historical background that led to the existence of the current national strategies. Additionally, our report, A Crisis Exploited (9), highlights various stakeholders and their conflicts of interests, as well anti-trust violations taking place by private-equity firms, pain advocacy groups, non-governmental organizations and academia with the assistance of our lawmakers and the media outlets.

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 (10). This change was made without notification/request for public input with the FDA claiming it was "impractical" to collect public feedback. It is highly unorthodox for federal agencies to change rules and regulations without public input.

A review of the work by U.S. federal agencies and their associated partners reveals a vigorous effort to integrate human clinical investigations into the private healthcare system. The FDA and other 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 obtaining the desired research. This is a clear admission by the stakeholder's that they are keenly aware that the majority of patients would not participate in these research projects if given a choice. In response to this

reality, the public, private-partners advocated for changes to the federal rules, regulations and legal issues that would permit decentralized-pragmatic clinical trials to be embedded in the private patient encounter; thus, circumventing informed consent, in an effort to gather the necessary data to conduct the desired clinical investigations.

Academic institutions and their representatives lobbied to change the rules and regulations of clinical practices to permit the pursuit of projects otherwise unattainable due to a lack of participation from research subjects. Clinical researchers would now be able to provide solutions to our nation's most complex and costly societal issues pending the ability to engage private citizens in the human clinical trials. These investigations were promoted and considered "minimal risk" to the patient. In application, these healthcare delivery system changes resulted in the denial of evidence-based treatments for patients, now forced to participate in unproven modalities for extended periods of time. This practice is not minimal risk and violates the individual's rights. These public health policy changes resulted in severe harms for patients who had their opioid medications abruptly discontinued with patients now contemplating and/or committing suicide to escape the debilitating pain they were now forced to endure.

The impact of these actions cannot be understated. The delivery of private medical care has been changed ***on the front-end*** to enable the use of electronic medical records in clinical research. This research is then used to change public-health policy and medical guidance, often done via a committee devoid of individuals who need opioid based medications to manage their overall health and well-being. These committees are solely assembled with the goal to create policy that declares medical use of opioids ineffective. Studies are not pursued to quantify the negative

outcomes resulting from these changes. There seems no desire to quantify these outcomes as they conflict with (as they are in direct opposition to) the predetermined national goals to restrict opioid analgesics to the citizenry, even in the direst of circumstances. This is not only unethical; it is scientifically irresponsible as it endangers the public's health and well-being.

Before moving forward with the next decade of this work, we need to examine what has been done so far and take action on any activities that have caused negative outcomes so they are not carried forward into future public-health policy changes.

The lack of formal oversight and transparency to the public has caused serious issues within the public, private-partnership structure. Our lawmakers have a duty to ensure the safety and well-being of all citizens. The current structure of the opioid-sparing policies in the nation are highly exclusionary and lack meaningful insight from the people who live with the painful illnesses and conditions; those who necessitate opioid analgesics to maintain any level of function.

Future committees must include individuals and organizations whose primary interest is to protect the rights and health of individuals who do not respond to these alternative therapies and require opioid based medications to manage their overall health. Rather than approaching the issue of medicinal access to opioids from a prohibitive standpoint (with the goal to reduce access at all costs), we should be approaching these investigations with focus on creating a true precision medicine model that provides the best treatment to the right patient, at the right time. Until we do this, we will continue to see these systemic issues in the healthcare system, along with unrealized overdoses, suicides and other negative health outcomes.

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