



Addressing
the
Tri-Crisis



A Blueprint for
the Next
Administration

Executive Summary



The Chronic Illness Advocacy & Awareness Group, Inc. (CIAAG) is a national non-profit organization that promotes both a common-sense, compassionate and research-based approach to palliative care along with the responsible prescribing of opioid medication to those experiencing chronic pain and illnesses, including: serious injuries, intractable pain, and those who suffer from painful chronic diseases.

CIAAG's mission is to work collaboratively with legislators in crafting the policy changes and legislation enacted to combat opioid abuse (including heroin and illegally-obtained fentanyl) in a way that does not restrict patients' access to their medication. Restricting access is not just a problem for the individual; it negatively impacts the nation's public and economic health, resulting in previously functioning members of society being forced into unemployment and disability in response to the relentless, inhumane and debilitating pain they experience.

Intractable pain and forced isolation often leads to depression and other mental health crises as well. Unfortunately, some patients have turned to the street to find unsafe alternatives (including dangerous counterfeit pills) in a desperate effort to relieve their untreated pain, while others have succumbed to suicide as a final escape.

CIAAG offers lawmakers and other decision-makers fact-based research on prescription opioid use from qualified physicians, as well as policy white papers, testimonials and other resources to aid in crafting sensible policies around opiate use.

CIAAG is a 501(c)(3) Non-Profit Organization, therefore any and all donations are 100% tax deductible.

Bios

Lauren Deluca, CPCU



Position:
**Executive Director &
Founding President**

Lauren Deluca, Founding President, graduated from Nichols College with a Bachelor's Degree in Finance. She earned several professional designations including, Charter Property Casualty Underwriter with a concentration on Commercial Insurance, Associates in Personal Insurance and Associate in General Insurance. She spent her career working as a Commercial Insurance Account Executive & Risk Manager specializing in Large & Middle Market accounts.

After a life altering medical emergency she Founded Chronic Illness Advocacy & Awareness Group to raise awareness of the impact healthcare policy changes are having on individuals with chronic illnesses, disease and conditions.

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Shasta Rayne Harner



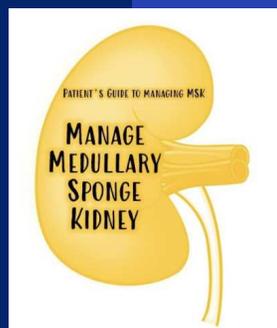
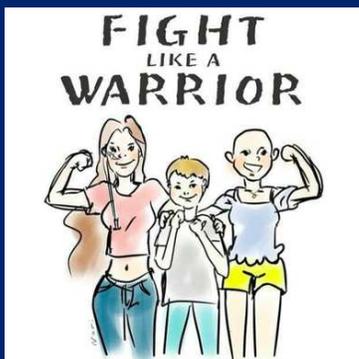
Position:
Vice President

Shasta Rayne Harner, Director & Vice President, graduated from Sonoma State University with a Bachelor's Degree in Political Science. She worked for many years as a Certified Medical Assistant and Project Coordinator for a large medical group. During the course of her career, she focused on the delivery of patient care to medical practice administration. Shasta lives with a rare, disabling auto-immune disease; dermatomyositis.

After the onset of her disease, Shasta gained insight into the experience of being a chronically ill patient in today's medical/political climate. As a result of this experience combined with her work history, personal interests, disability and educational background, she was inspired to advocate for others who also live with disabling diseases and conditions.

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Our Coalition Partners





Executive Summary

The United States is currently facing a unique challenge; one that consists of balancing a dual role of ensuring equitable access to scheduled medications, including opioid analgesics, along with working to prevent illicit drug abuse and diversion.

Over the past several years there has been an abundance of work done to combat the issue of substance misuse with a particular focus on prevention. Additionally, billions of dollars have been allocated to a number of federal programs including the HEAL Initiative, National Pain Strategy, the National Institutes of Health and the Patient Centered Outcomes Research Institute (PCORI), among others, to develop alternative treatments for chronic pain, cancer pain and palliative care as part of this goal.

Daily chronic pain is an issue that faces over 100 million Americans with 50 million suffering from daily high-impact pain that impacts their quality of life. Additionally, the issue of chronic pain costs the nation over 635 million dollars annually in lost opportunity costs, disability, healthcare and other related costs.

As a result, the Affordable Care Act along with other legislation, including the Comprehensive Addiction Recovery Act (CARE Act) and The SUPPORT Act have passed a number of measures to combat this national public health issue.

Unfortunately, in doing so, we have revealed a number of systemic implementation issues that have created a subsequent public health emergency of under and untreated pain as well as wide-spread civil right abuses/violations against the very individuals these laws set out to assist.

Chronic Illness Advocacy & Awareness Group's (CIAAG) goal is to work with the community, legislators and other stakeholders to educate them on the patient experience and on how current public health policy changes are impacting the individual health of the consumer and in turn, the economic health of the nation.

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We urgently need a new approach for access to medicines as it relates to individuals who need opioid analgesics to manage their complex illnesses/conditions. We cannot wait years before we act. The time is now.

CIAAG is a coalition of healthcare organizations, disease groups, patient rights, privacy and data rights, civil rights, and physician groups that have come together to preserve the personal autonomy of the citizenry of the United States and their rights to choose the medications that provide them the highest quality of life. We are advocating for federal legislation and action by government agencies to protect individuals from discriminatory healthcare practices.

While some solutions are legislative, we encourage the administration to model exemplary human and civil right protections: by eliminating bias and the growing disparities in government programs; encouraging robust and meaningful agency enforcement; ensuring balanced representation on future healthcare committees and opioid task forces and supporting action in Congress to enact effective legal protections.

To that end, we urge you to adopt the following action items starting next year. We make ourselves available at your disposal to assist drafting any orders, memos, and policies mentioned below.

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Action 1: Perform an Impact Assessment

- **Recommendations for Day One**

- Send a memorandum across the administration advising of the need for impact assessments specifically related to access to opioid analgesics and subsequent increases/decreases in suicide, medical errors, disability or other forms of medical decline - whether it be mental or physical.

- **Recommendations for First 100 Days**

- Impact assessments and related reports should be provided to all appropriate agencies including but not limited to: the Department of Health and Human Services, the National Institutes of Health, The Centers for Disease Control and Prevention, Center for Medicare/Medicaid Services, Department of Defense, Agency for Healthcare Research & Quality, the Food & Drug Administration, the National Governors Association, the National Association of Attorneys General. Additionally, copies should be available to the public through one or more of these agencies websites.
- Direct all agencies with civil rights authorities to evaluate discriminatory practices as related to access to opioid analgesics. The previous administration's efforts permitted a number of concerning actions as related to directives in the Affordable Care Act as it pertains to the National Pain Strategy and other programs. Such an instance was the approval of the FDA to remove [informed consent](#) as it relates to human clinical studies, which is a direct violation of the [Belmont Agreement](#) and the [United Nations Human Rights Agreement](#). We must ensure the steps taken to address drug abuse do not interfere with the civil and human rights of citizens in need of other healthcare services.

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- Direct agencies not to adopt the use of dose caps on opioid prescriptions as previously stated by the [CDC](#), [FDA](#) and [HHS](#) in 2018. This has been proven to be a dangerous suggestion that has led to increased suffering and even death among individuals with chronic illnesses/conditions. Additionally, this has been disavowed as “evidenced based/best practices” by the American Medical Association in their [letter](#) dated June 16, 2020.
- Establish an Interagency Task Force on Access to Opioids, with participation from HHS, CDC, FDA, DoD, DOJ, and other relevant agencies with the goal of developing tools to identify and eliminate healthcare practices with disparate impact. It is vital this task force consists of individuals that will ensure the best interests of those with serious illnesses in need of palliative care services are met. Additionally, these individuals should not possess undue financial ties to the pharmaceutical, behavioral health, alternative care, complementary care, data/privacy industry or the substance use/recovery industry. In order to solve the tri-crisis of substance use disorder, access to alternative care and access to opioids, we must address each of these three issues in an equitable manner which includes the proper, balanced representation for each of the three communities with the full support from the administration.

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Action 2: Include Qualified Pain Management Specialists & Patient Advocates on the Opioid Task Forces and Committees

- **Recommendations for Day One**

- Review the composition of all federal opioid task forces and committees for conflicts of interest and remove/replace individuals found to have undue financial ties to the pharmaceutical industry, behavioral health industry, recovery industry, alternative/complementary health, data/privacy industry and/or insurance industry. Additionally, a minimum of two patient advocates, focused on the delivery of palliative care, should be appointed to all federal committees.

- **Recommendations for First 100 Days**

- Create a centralized website to provide updates from all federal agencies related to their activities to address the opioid crisis, including, related work regarding pain management and access to opioids.
- Ensure transparency of the past, current and future work/plans of the federal agency opioid task forces to be regularly updated and provided to the public via a centralized website to be managed by a newly appointed Opioid Crisis Accountability Coordinator. Currently, data is not available to the public in a timely manner which has created an environment where these work groups can go unopposed and recommend/implement policies that may not be in the best interest of the public health and well-being. The addition of a centralized website will resolve this issue and enable more participation from the various stakeholders involved.

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Action 3: Ensure Patient Privacy & HIPAA Compliance

In recent years the use of data has become a growing part of “doing business” especially as it relates to healthcare. Along with this comes the responsibility to simultaneously maintain the integrity of the collected data and the privacy protections of the individual’s data being accessed.

While the Federal Trade Commission (FTC) helps to safeguard consumers and promote competition, they lack rulemaking authority on privacy related issues. The United States needs a federal agency focused on privacy protection/compliance with data protection obligations that is prepared to manage emerging privacy challenges.

Recommendations for First 100 Days

- Establish a Federal Data Protection Agency.
- Appoint a task force to address how to bring data, privacy, and digital rights under a single silo to address the coordination/implementation and to combine these public services as such.
- The task force should also examine the social, ethical, and economic impacts of high-risk data processing, such as that being undertaken in the healthcare setting as we move towards the biopsychosocial model of care. There are concerns the new model of care will create a healthcare system filled with systematic discrimination built into the algorithms thus preventing underserved populations (black/brown, immigrants, disabled, women, elderly) from accessing the necessary services they need.
- Prepare a report regarding the findings of the task force and their recommendations to ensure protection of consumers privacy and civil rights as related to data collection being performed by various federal agencies and private business enterprises.

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- Outline disparities found within the report and make recommendations for regulatory or legislative changes to address issues found and ensure consumer privacy protections.

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Action 4: Remove Incentives to Promote Denial of Opioid Analgesics

- **Recommendations for First 100 Days:**
 - The HHS Pain Management Task Force’s recommendations in their “Pain Management Report” has created a number of systematic barriers to accessing appropriate pain management for individuals with serious illnesses and conditions. Additionally, they are recommending a “fail first” / step-therapy approach to the treatment of pain which can lead to [serious consequences](#) for the individual patient. Delay of appropriate care can mean the difference between full recovery and a total disability.
 - Instruct CMS to [de-incentivize](#) the denial of opioid analgesics for postoperative patients. It is unethical and creates a conflict of interest for a surgeon to have financial incentives to withhold a medication from a patient. It is imperative consumers are receiving individualized care based on their specific needs. This incentivizing of the denial of appropriate pain care creates a situation where the decision-making process is coming from a financial mindset rather than based on the patient's true needs. Additionally, doing so directly impacts the results of clinical research (pragmatic clinical trials) taking place and the record may reflect medications were not needed when they were. The patient outcome would be recorded as “successful” thus leading the data to support the idea that patients “don’t need post-op pain medication”, when in reality they do, the medication was withheld due to financial incentives and the patient suffered greatly. Doctors will not report patients did poorly (without opioids) as they would be violating their duty to the patient and potentially liable for malpractice. Therefore, tainting the data being collected which will further exacerbate the issue we are currently facing.

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Action 5: Increased Transparency & Oversight Into the Population Studies

- **Recommendations for First 100 Days**
 - Establish an oversight committee to review the work being undertaken by the National Institutes of Health, National Pain Strategy, Inter-Agency Pain Research Coordinating Committee, the HEAL Initiative, Patient Centered Outcomes Research Institute, Agency for Healthcare Research and Quality, Centers for Disease Control & Prevention, Veterans Association, Department of Defense as it relates to pain research, in particular pragmatic clinical trials taking place throughout the nation.
 - Support a Congressional Hearing with the Drug Enforcement Agency to address their protocols relating to investigations alleging “overprescribing.” Additionally, there must be accountability for displaced patients when the DEA raids physician offices. These raids often lead to the displacement of a large number of legitimate patients and as a result, puts the patients in a potentially life threatening situation due to the disruption of their continuity of care.
 - Review the [DEA Request](#) for accessing additional patient data for privacy concerns. It has been proven by clinical studies that prescribing is not the root cause of addiction with [less than 3%](#) of individuals developing Opioid Use Disorder from a legitimate prescription. The pursuit of illicit drug abuse cannot take precedence over individual privacy rights and access to healthcare/medicines.
 - [FDA Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects](#) must be rescinded in its entirety. If the research being

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conducted carries no risk of harm to the patient, then there should be no issue with obtaining consent. Consent is a vital human right. We all should maintain personal autonomy to what does or does not happen to our own bodies. Additionally, the waiver leaves it up to judgement of a third party to determine what they deem to be “minimal risk.” As we have seen with the forced tapering experiment conducted by HHS in recent years, the failure to provide adequate pain care, including appropriate access to opioid analgesics, has caused maximum damage with individuals committing suicide as a result. The FDA Waiver has permitted this to take place and must be rescinded to ensure we are in compliance with the Belmont Agreement as well as the United Nations Human Rights Agreement.

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Action 6: Raise Awareness & Advocate Against the Stigma Placed Upon People Living with Painful Conditions and/or Illnesses

- **Recommendations for First 100 Days**
 - Recognize there is a tri-crisis in the United States rather than a dual crisis as originally thought during the creation of the National Pain Strategy. Over the past several years we have seen a subpopulation of patients emerge that do very well on opioid medications (improved function and quality of life) that do not respond to other forms of treatment. When these individuals lose access through forced tapering, it often results in medical decline, as well as suicide. It is imperative for the United States to achieve the goals outlined in the National Pain Strategy, the Healthy People campaign, among other federal and international strategies; therefore, we must work together on the tri-crisis with respective representatives from all three communities participating.
 - Support the allocation of federal monies to the states to create and implement public awareness campaigns about the impact of untreated pain and the tri-crisis facing our nation.
 - Send a memo to various agencies to ensure all programs related to raising awareness of opioid abuse include detailed education regarding the differences between addiction and dependency, as well as the vital role proper palliative care has in patient care and harm reduction.
 - Support dual awareness campaigns for those suffering with substance use disorder and chronic pain. These communities must work together to create a de-stigmatizing language that serves the tri-communities.

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- Support a public awareness campaign educating our nation's youth that the pills they receive from a "friend" (or at a party) may not be a pharmaceutical grade product; therefore, can potentially be laced with other unknown, dangerous substances. Failure to put forth a concentrated effort into a campaign educating the nation of this vital fact has contributed to the overdose crisis as there is a false sense of security that taking "pills" that are medical grade is "safe" when it is not.

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Action 7: Support Legislative Action “Equal & Fair Access to Palliative Care”

Recommendations for Legislative Action:

Support federal legislation that includes clear language relating to the treatment of palliative care and access to opioid analgesics as a basic human right.

- Amend the federal definition of “palliative care” to align with the World Health Organization. This would ensure that those with refractory and/or debilitating conditions (incurable and/or curable) that necessitate the alleviation of their symptoms of their condition/illness, receive the treatment and care they need.
- Add language reinforcing the United States commitment to the United Nations Human Rights Agreement, which requires nations to provide morphine for their citizens as a basic human right to alleviate suffering.
- Our executive team and coalition partners are available to assist with the development of the bill’s language.

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Action 8: The HHS Proposed Unprecedented Regulatory Reform through Retrospective Review

- **Recommendations for First 100 Days**
 - Obtain and publish for public review a full list of the regulations to be reviewed as a part of the [HHS Regulatory Reform through Retrospective Review](#) of all past regulations.
 - Send a memorandum to HHS advising the establishment of a website/portal where all regulations up for review are listed along with the planned “actions” to ensure maximum public transparency and participation in the process. This includes the publication of the proposed comment collection and public testimony dates with accommodations allotted for virtual testimony to take place due to the COVID-19 pandemic. This will allow for maximum participation in the process and therefore, is not exclusive to the elite/special interests with the money and ability to get people flown in to testify.



Action 9: Ensuring balance in the Administration's plan to pursue two joint goals: eliminate over-prescribing for prescription opioids for pain, and improve the effectiveness of and access to alternative treatment for pain

- **Recommendations for First 100 Days**

- We appreciate the administration's commitment to ensuring access to complementary and alternative care for the management of chronic pain. However, we urge the administration to be mindful that there is a subpopulation of individuals who require pharmacological management of their conditions/illnesses. These individuals must be ensured access to the medications and treatments that provide them the best quality of life without having to submit to "fail first" protocols of alternative/complementary treatments before they are afforded pharmacological options, as recommended by the HHS Pain Management Task Force's report on what is being presented as "best practices."
- While the administration has committed to the research of alternative non-opioid medications, we must recognize there are millions of citizens who need pain care now. These individuals cannot wait years for the development of new drugs/treatments, which may or may not be effective and must be afforded access to the medications that provide them the best quality of life.
- Send a memorandum to all federal agencies advising of the administration's commitment to guaranteeing the appropriate palliative care, focused on improving the quality of life, for those with chronic illnesses, diseases and other incurable conditions.

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- Acknowledge that prescribing is not the root of the overdose crisis. There are an abundance of studies showing that individuals prescribed opioid pain medications often do well and do not become addicted. The continued focus on the idea of “overprescribing” has resulted in the exacerbation of the overdose crisis in America as well as a dramatic increase in patient suicides due to untreated pain. We as a nation must come together on a plan to combat drug abuse while ensuring and preserving the personal autonomy of those who need access to pain medications to treat their chronic illnesses/conditions. The administration's plan to focus on overprescribing will lead to further exacerbation of the tri-crisis. Our executive team is available to provide additional resources/research to support the administration's decision to shift away from this policy.

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