FOR IMMEDIATE RELEASE - May 12, 2019

TO: The Pain Community

FROM: Pain Warriors Unite

RE: ***Overview of Pain Management Task Force Meeting & Recommendations***

View Task Force's Final Report HERE

The purpose of this final meeting was for the Task Force members to disseminate and discuss the **final report** in full detail. They debated and deliberated to carefully refine the language and terminology to avoid future misinterpretation or misapplication. They reviewed the consensus of thousands of comments submitted by the public during the previous public comment periods.

We've followed the Task Force's progress throughout the last year, and it's apparent that their main priority emphasizes that doctors should use **clinical judgement** to determine an individualized treatment plan in conjunction with their patients input which includes opioid pain medication when appropriate, in addition to other tools/modalities.

These principles have always been the norm for treating pain in long term, complex patients, but many options have been underutilized by doctors and payers for various reasons.

The Final Report including all latest revisions is slated to be **released** by the end of May. We will post the Finalized Report & Webcast Archives once they become available.

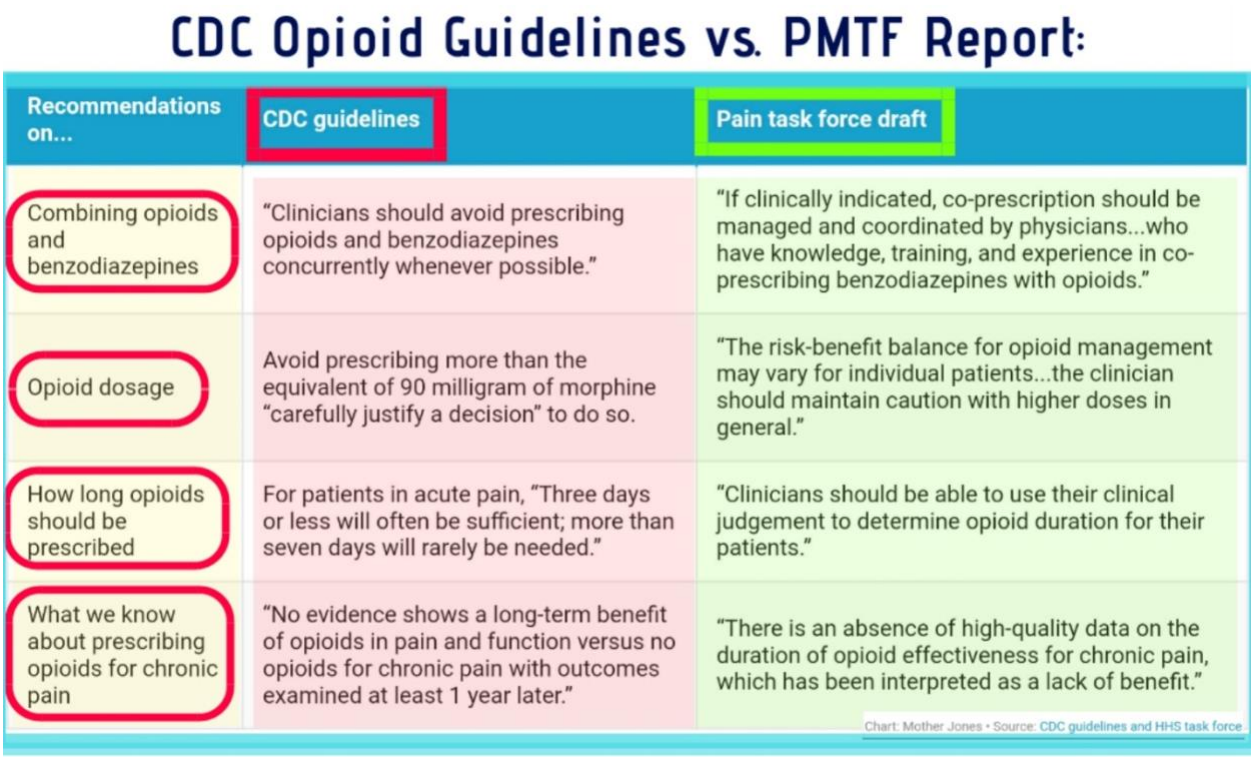
Please review our evaluation of the Task Force meeting and report below, followed by the 3 page Executive Summary from the Report.

For the Naysayers and Pessimists

The HHS Pain Management Task Force and its Draft Report has been repudiated by anti opioid zealots, Andrew Kolodny, PROP, legislators, reporters, **NAAG** and 39 State Attorneys General because according to them, the report "deviates from the CDC Guideline" and "significantly watered down the guideline". According to PROP, if the Task Force's recommendations become our national pain policy, it will "open the doors of **mass prescribing**" and cause further deaths & addiction. They've even accused specific members of being **shills** for Big Pharma, including Task Force Chair, Dr. Vanila Singh who has been our greatest ally.

> Lembke, the Stanford addiction director, worries that as is, the draft recommendations are "promoting the very same myths about opioid prescribing that got us into this mess in the first place: That no dose is too high, that risk assessment tools can predict who will get addicted, and that combining opioids and [benzodiazepines] has 'clinical value.'"

If the task force recommendations were excessively **detrimental** to the pain community, the anti opioid zealots wouldn't be stomping their feet declaring that the report is a "huge step backwards" and will essentially "erase 3 years of progress" made to reduce prescribing, addiction, and overdose deaths. See article **HERE** from Mother Jones and comparison chart below.



In the Scheme of Things

There are approximately **50 million** Americans who suffer from chronic pain, out of which several subpopulations exist, including roughly **19.6 million** who suffer from debilitating **chronic high impact pain -** defined as pain lasting 3 months or longer that restricts daily major life or work activities.

It is estimated that approximately **5 million high impact pain patients** require high dose (above 90 mme) opioid therapy. In the grand scheme of things, **we are truly the minority**, which explains why we aren't seeing the huge response from fellow pain warriors as we had expected.

We've known from the start that the Task Force was not going to suggest the CDC Guideline be "scrapped" and/or rewritten, and for any of us to expect that would have been the final outcome of this meeting is just NOT feasible. We need to accept it for what it is and build on the areas that are helpful to our collective cause. No, it's not exactly what we would like it to be, but it's a heck of a lot better than the status quo. Collectively, we believe it's significant progress and a "happy medium" that should satisfy stakeholders on all ends of the spectrum.

Key Takeaways:

▪ The Pain Task Force emphasized 5 treatment modalities for individualized patient-centered approach to pain management which include:

1. Medication
2. Restorative therapies
3. Interventional procedures
4. Behavioral Health approaches
5. Complementary & Integrative Health

▪ Addressed the stigma associated with pain and painful illnesses through education and awareness.

▪ Removes and/or adjusts language pertaining to limitation of medication dosage and duration.

▪ Encouraged policies that emphasize individualized patient treatment plan based on the decision between doctors and patients.

▪ Support multimodal approach for treating acute and chronic pain.

▪ Acknowledged concerns of weaponization and misapplication of Guideline and PDMP by DEA, DOJ, and other State and Federal Agencies.

▪ Recognized the benefit of higher doses of opioid medication and/or co-prescribing benzodiazepines has clinical value in some patients.

Excerpt from Report:

*The idea of a **ceiling dose** of opioids has been recommended, but establishing such a ceiling is difficult, and the precise level for such a ceiling has not been established. The risk of overdose increases with the dose, but the therapeutic window **varies considerably** from patient to patient. For example, the CDC guideline identified a dose limit of 90 MMEs per day. A more recent study evaluated the risk of death related to opioid dose in 2.2 million North Carolinians and found that the **overall death rate was 0.022% per year**. The researchers noted that:*

- *"Dose-dependent opioid overdose risk among patients increased gradually and **did not show evidence of a distinct risk threshold**. Much of the risk at higher doses appears to be associated with co-prescribed benzodiazepines. It is critical to account for overlapping prescriptions, and justifies taking a person-time approach to MME calculation with intent-to-treat principles."*

▪ **Educate ALL stakeholders from patients to policy makers about the impact of pain and the barriers patients and prescribers are faced with as a result of increased regulations and legislation.**

Excerpt from Report:

Policymakers, regulators and legislators at both the federal and the state level play an important role in formulating policy, issuing guidelines and direction, and passing legislation on issues related to acute and chronic pain management, payment mechanisms, and the use and regulation of controlled medications. The issue of pain management is complicated, so ***every*** *decision made, law passed, or guideline issued has a* ***cascading effect*** *on many aspects of pain management. As such, a deep understanding of the issues, especially the potential for unintended consequences of these decisions, is essential in formulating effective comprehensive policy.*

POLICYMAKER, REGULATOR AND LEGISLATOR EDUCATION & POLICY EVALUATION

Gap 1: Current ***education for policymakers*** *at the state and federal level has significant opportunities for improvement for both acute and chronic pain.*

• *Recommendation 1a: Strongly encourage education by key and relevant expert stakeholders from the appropriate professional associations, clinicians, and patient advocacy groups prior to effecting policy on acute and chronic pain.*

• *Recommendation 1b: Establish criteria for evaluating legislation and regulation based on the principles in the preamble of this report ensuring an understanding of all potential unintended consequences of guidelines, policies, regulations, or legislation that is being considered.*

EXECUTIVE SUMMARY

Patients with acute and chronic pain in the United States face a crisis due to significant challenges in obtaining adequate care, resulting in profound physical, emotional, and societal costs. According to the Centers for Disease Control and Prevention (CDC), 50 million adults in the United States have chronic daily pain, with 19.6 million adults experiencing high-impact chronic pain that interferes with daily life or work activities. The cost of pain to our nation is estimated at between $560 and $635 billion annually. At the same time, our nation is facing an opioid crisis that, over the past decade, has resulted in an unprecedented wave of overdose deaths associated with prescription opioids, heroin, and synthetic opioids.

The Pain Management Best Practices Inter-Agency Task Force (Task Force) was convened by the US Department of Health and Human Services (HHS) in conjunction with the Department of Defense (DOD) and the Veterans Administration (VA) with the Office of National Drug Control Policy (ONDCP) to address acute and chronic pain in light of the ongoing opioid crisis. The Task Force mandate is to identify gaps, inconsistencies, and updates, and to make recommendations for best practices for managing acute and chronic pain. The 29 member Task Force included federal agency representatives as well as non-federal experts and representatives from a broad group of stakeholders. The Task Force considered relevant medical and scientific literature and information provided by government and non-government experts in pain management, addiction, mental health and representatives from various disciplines. The Task Force also reviewed and considered patient testimonials and public meeting comments, including approximately 6,000 comments from the public submitted during a 90-day public comment period and 3,000 comments from two public meetings.

The Task Force emphasizes the importance of individualized **patient-centered care in the diagnosis and treatment** of acute and chronic pain. This report is broad and deep and will have sections that are relevant to different groups of stakeholders regarding best practices. It is encouraged to see the table of contents and the sections and sub-sections of this broad report to best identify that which is most useful for the various clinical disciplines, educators, researches, administrators, legislators and other key stakeholders.

The report emphasizes the development of an effective pain treatment plan after proper evaluation to establish a **diagnosis** with **measurable outcomes that focus on improvements including quality of life (QOL), improved functionality, and Activities of Daily Living (ADLs)**. Achieving excellence in acute and chronic pain care depends on the following:

- An emphasis on an **individualized patient-centered** approach for diagnosis and treatment of pain is essential to establishing a **therapeutic alliance** between patient and clinician.
- Acute pain can be caused by a variety of different conditions such as trauma, burn, musculoskeletal injury, neural injury, as well as pain due to surgery/procedures in the perioperative period. A **multi-modal approach that includes medications, nerve blocks, physical therapy and other modalities should be considered for acute pain conditions.**
- A **multidisciplinary** approach for chronic pain across various disciplines, utilizing one or more treatment modalities, is encouraged when clinically indicated to improve outcomes. These include the following five broad treatment categories. These categories have been reviewed with an identification of gaps/inconsistencies with recommendations for best practices:
    - **Medications: Various classes of medications,** including non-opioids and opioids, should be considered for use. The choice of medication should be based on the pain diagnosis, the mechanisms of pain, and related co-morbidities following a thorough history, physical exam, other relevant diagnostic procedures and a **risk-benefit assessment that demonstrates the benefits of a medication outweighs the risks.** The goal is to limit adverse outcomes while ensuring that patients have access to medication-based treatment that can enable a better quality of life and function. Ensuring **safe medication storage** and **appropriate disposal of excess medications** is important to ensure best clinical outcomes and to protect the public health.

  - **Restorative Therapies** including those implemented by physical therapists and occupational therapists (e.g., physiotherapy, therapeutic exercise, and other movement modalities) are valuable components of multidisciplinary, multimodal acute and chronic pain care.
  - **Interventional Approaches** including image-guided and minimally invasive procedures are available as diagnostic and therapeutic treatment modalities for acute, acute on chronic, and chronic pain when clinically indicated. A list of various types of procedures including trigger point injections, radiofrequency ablation, cryoneuroablation, neuro-modulation and other procedures are reviewed.
  - **Behavioral Health Approaches** for psychological, cognitive, emotional, behavioral, and social aspects of pain can have a significant impact on treatment outcomes. Patients with pain and **behavioral health comorbidities** face challenges that can exacerbate painful conditions as well as function, QOL, and ADLs.
  - **Complementary and Integrative Health,** including treatment modalities such as acupuncture, massage, movement therapies (e.g., yoga, tai chi), spirituality, among others, should be considered when clinically indicated.

- Effective multidisciplinary management of the potentially complex aspects of acute and chronic pain should be **based on a biopsychosocial model** of care.
- Health systems and clinicians must consider the pain management needs of the **special populations** that are confronted with unique challenges associated with acute and chronic pain, including the following: children/youth, older adults, women, pregnant women, individuals with chronic relapsing pain conditions such as sickle cell disease, racial and ethnic populations, military active duty and reserve service members and Veterans, and cancer and palliative care.
- **Risk assessment** is one of the four cross-cutting policy approaches that is necessary for best practices in providing individualized, patient-centered care. A thorough patient assessment and evaluation for treatment that includes risk benefit analysis are important considerations when developing patient-centered treatment. Risk assessment involves identifying risk factors from patient history, family history, current biopsychosocial factors, as well as screening and diagnostic tools, including PDMP, laboratory data, and other measures. Risk stratification for a particular patient can aid in determining appropriate treatments for the best clinical outcomes for that patient. The final report and this section in particular emphasizes safe opioid stewardship with regular re-evaluation of the patient.
- **Stigma** can be a barrier to treatment of painful conditions. Compassionate, empathetic care centered on a patient-clinician relationship is necessary to legitimize the suffering of patients with painful conditions and to address the various challenges associated with the stigma of living with pain. Stigma often presents a barrier to care, and is often cited as a challenge for both patient, families, caregivers, and providers.
- Improving **education** about pain conditions and their treatment for patients, families, caregivers, clinicians and policymakers is vital to enhancing pain care. Patient education can be emphasized through various means including clinician discussion, informational materials and web resources. More effective education and training about acute and chronic pain should occur at all levels of clinician training, including undergraduate educational curricula, graduate professional training, and continuing professional education, including the use of proven innovations such as the Extension for Community Healthcare Outcomes (Project ECHO) model. Education for the public as well as for policymakers and legislators is emphasized to ensure expert and cutting-edge understanding is part of policy that can affect clinical care and outcomes.
- Addressing **access to care** barriers is essential to optimizing pain care. Recommendations include addressing the gap in our **workforce** for all disciplines involved in pain management. Additionally, improved **insurance coverage and payment** for different pain management modalities is a critical component in improving access to effective clinical care, and should include coverage and payment for care coordination, complex opioid management and

telemedicine. It is also important to note that in many parts of the country patients will only have access to a primary care provider. Support for education, time and financial resources for primary care providers (PCPs) is essential to manage these patients with painful conditions.

- **Research and Development:** Continued medical and scientific research is critical to understanding the **mechanisms underlying the transition from acute to chronic pain**, to translating promising scientific advances into new and effective diagnostic, preventive and therapeutic approaches for patients, and to implementing these approaches effectively in health systems.

A review of CDC Guideline (as mandated by the Comprehensive Addiction and Recovery Act [CARA] legislation): The Task Force recognizes the utility of the 2016 Guideline for Prescribing Opioids for Chronic Pain released by the CDC and its contribution to mitigating unnecessary opioid exposure and the adverse outcomes associated with opioids. It also recognizes unintended consequences that have resulted following the release of the guidelines in 2016, which are due in part to misapplication or misinterpretation of the guideline including forced tapers and patient abandonment. The CDC recently authored a pivotal article in the New England Journal of Medicine (NEJM) on April 24, 2019, specifically re-iterating that the CDC Guideline has been, in some instances, misinterpreted or misapplied.[1] The authors highlight that the guideline does not address or suggest discontinuation of opioids prescribed at higher dosages. They note "policies invoking the opioid-prescribing guideline that do not actually reflect its content and nuances can be used to justify actions contrary to the guideline's intent." Educating stakeholders about the intent of the guideline (as it relates to the use of opioids for chronic pain by primary care clinicians), reemphasis of the core benefits of the guideline, and encouraging optimal application of this guideline are essential to optimizing acute and chronic pain care. (Please see Section 4 Review of the CDC Guideline in the attached Task Force report).

The Task Force, which included a broad spectrum of stakeholder perspectives, was convened to address one of the greatest public health crises of our time. The Task Force respectfully submits these gaps and recommendations, with special acknowledgement of the brave individuals who have told their stories about the challenges wrought by pain in their lives, the thousands of members and organizations of the public sharing their various perspectives and experiences through public comments, and the millions of others they represent in our nation who have been affected by pain.