2022

CIAAG

CHRONIC ILLNESS ADVOCACY
& AWARENESS GROUP

CDC OPIOID PRESCRIBING GUIDELINES (DRAFT)

A CIAAG ANALYSIS

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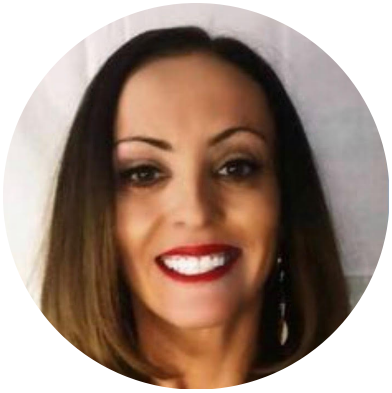

Lauren Deluca
Executive Director &
Founding President

From the President

Since CIAAG was Founded in 2017 our organizational mission has grown into a complex set of priorities to protect the civil liberties of all individuals.

CIAAG has expanded our focus to encompass a broad array of issues related to the restructuring of the healthcare systems within our nation and beyond.

While we started with a focus on access to opioid analgesics, we quickly learned the vast complexity of public-health policy landscape. The US Federal Government has embarked upon the use of Pubic-Private-Partnership's in a manner never done before. As such, much of the necessary regulatory oversight and safety mechanisms have yet to be established.

CIAAG provides consultative services to guide public-health policy changes that meet both the private and public good.

In doing so, we seek to create powerful partnership to build a healthcare system that is both economically viable and socially acceptable.

Lauren L. Deluca, CPCU
Executive Director & Founding President

CIAAG Analysis

> **The 2022 CDC Opioid Prescribing Guideline (draft) is nothing more than an attempt to lock in the recommendations made by the HHS Pain Management Task Force into public health policy before they receive the necessary Congressional support or even clinical evidence of their efficacy.**
>
> **-Lauren Deluca, CPCU**

In 2016, the Centers for Disease Control & Prevention published national Opioid Prescribing Guidelines which recommended dose caps and other restrictions on the prescribing of opioid analgesics for the purposes of treating pain.

Upon implementation of the 2016 Opioid Guidelines, patients across the nation began to have previous stable regimens of opioid based medications denied by their providers and many were put through dangerous, abrupt discontinuation of their medications which lead to medical destabilization and even patient suicides.

As required by federal mandate, after 5yrs the CDC was required to assemble a group of stakeholders to update their Opioid Prescribing Guidelines based on newly emerging science. As such, the CDC published their draft version of the 2022 Opioid Prescribing Guidelines on February 10, 2022.

Summary

2022 CDC Draft Revision of the Opioid Prescribing Guidelines

- First and foremost our team reviewed the composition of the individuals involved in the 2022 Opioid Prescribing Guidelines and discovered the CDC appointed numerous individuals with well-known personal and/or financial conflicts of interest. The most disconcerting is Roger Chou, MD.

  Roger Chou, MD has worked with well-known anti-opioid advocacy organization's, such as PROP for many years. The research projects he has been involved in have largely been focused on **discrediting** the safe, effectively use of opioid based medications. Often times, producing research that appears to be heavily influenced by opinion rather than scientific evidence.

  Additionally, he was involved in 2 of the 5 systematic evidence-reviews performed by AHRQ that were used to update the CDC 2022 Opioid Prescribing Guidelines. He should not have been permitted on both the AHRQ committees and CDC Guideline re-write committee as this creates potential bias in the ultimate recommendations made.

  Roger Chou, MD served on the CDC Core Expert Group that advised the CDC during the drafting of the 2016 Opioid Prescribing Guidelines which came under scrutiny for violating the Federal Advisory Committee Act.

  Finally, he previously served on an Oregon state task force in which it was recommended to abruptly discontinue opioid based medications for Oregon Medicaid patients regardless of diagnosis. The policy was only scaled back due to public backlash from patients who said the recommendations were not supported by evidence nor were they compassionate.

Summary

2022 CDC Draft Revision of the Opioid Prescribing Guidelines

- A dominating theme throughout the report is the authors' use of their own personal research projects as "supporting evidence" for the recommendations they are making. Particularly, Roger Chou's work was **cited 99 times** of times alone. In addition, both Deborah Dowell and Beth Darnall's research was also frequently cited throughout the report as well. This gives serious concerns about bias contained within the recommendations and/or questions about the validity of the evidence-base used by the committee.

- In reviewing the recommended therapeutic options, we see the authors repeatedly state these modalities "may be effective" as treatments. However, in reviewing the outcomes of the AHRQ Systematic Review, they acknowledge that these same modalities are shown to have either "limited evidence" or "no-evidence" for reducing pain or improving function. Additionally, the HHS Pain Management Task Force outlined recommendations for a number of these modalities the be further researched due to existing evidence-gaps. Yet, these same modalities are being recommended by the authors to be the primary treatment option for a number of illnesses/conditions. Needless to say, this is extremely concerning as the authors should not be recommending treatment modalities that are inadequately studied and/or previously proven ineffective to be implemented into patient care at the clinic. This begs the question, why would the authors recommend implementing modalities into clinic practice when their efficacy is minimal and/or limited?

- The authors make the assertion that there is a lack of evidence to support the use of opioid analgesics for more than 1 year. (Once again using Roger Chou's personal research as supporting evidence). However, it should be noted they acknowledged that studies >1 year were **not included** in the evidence review performed by AHRQ. Since the committee willfully excluded these types of studies from their review, it is unethical and deceiving to claim there is a lack of research to support their use. When in reality, they opted not to look at this research in the first place.

Summary

2022 CDC Draft Revision of the Opioid Prescribing Guidelines

- The committee opted to use outdated and misleading statistics in the report for seemingly no other reason that creating shock value to justify their recommendations. One instance of this is when the authors opted to cite that prescriptions for opioids increased four fold from year 1999-2010. Yet, later in the report they acknowledge that prescribing has dramatically ***decreased*** from the years 2012 - present day with current day prescribing back to pre-1993 levels. The mentioning of outdated statistics from 1999 - 2010 are truly irrelevant to the current state of the nations drug crisis. It would be far more appropriate for the committee to focus on current information rather than using outdated data to justify a failing agenda.

- The authors use the unsubstantiated claim of "inappropriate prescribing" as a major issue to that needs to be addressed. However, there is no legal definition for what is deemed inappropriate and therefore, this type of narrative should not be included within any formal guidance documents given its known ambiguity.

- Within the revised draft report the authors state: they (the CDC) "recognized a need for national guidance on pain management" and thus produced the 2016 CDC Opioid Prescribing Guidelines. However, this is misleading and factually incorrect. In reality, the 2016 Opioid Guidelines were created as a result of an Executive Order issued by President Obama. Why the authors opted to misrepresent this fact is unknown. Given this is a formal agency guidance report, the historical steps that led to its creation are of vital importance to help ensure the public's understanding of what is taking place and therefore, should be stated accurately.

- The authors acknowledge a lack of evidence for:

    * The effectiveness of opioid dosing strategies.
    * The effects of combination therapy versus opioid or non-opioids.
    * The benefits & harms of different methods for initiating or titrating opioids.

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2022 CDC Draft Revision of the Opioid Prescribing Guidelines

- The authors claim there was no intention for the 2016 CDC Opioid Prescribing Guidelines to be used for the creation of new regulations, laws and/or policies. However, approximately 40 states have passed legislation restricting opioid access since their issuance. Additionally, Medicaid programs have used the guidelines to create opioid edits in their pharmacy programs.. Oftentimes, directly referencing the 2016 CDC Opioid Prescribing Guidelines as the supporting rationale.

- Further, the authors make the assertion that these (opioid limiting laws) "might have had postive results for some patients." Given the overwhelming feedback from the patient community, this statement is not only factually incorrect, it is deeply hurtful and disrespectful to the millions of patients who have incurred medical injury and/or committed suicide as a result of these changes in prescribing laws. Additionally, it is important to note; there have been **no studies** to substantiate this claim. This is a clear personal opinion of the authors at best; or willful and intentional creation of misinformation for personal gains at worst.

- The authors state that "new evidence" has emerged since the 2016 Guidelines were issued. This has been an issue of contention between patient rights groups and the clinical research community (who deny the personal and professional gains they enjoy as a result of the restricted access to opioids). However, the statement made by the authors (and a review of the clinical trial database) supports that millions of dollars are going towards studying pain "in the real world" through the use of decentralized-pragmatic-clinical trials. While new research is generally a positive thing, this new approach to garnering research has created a system where unfounded theories are being implemented into the public-health system to be studied "real time" with the new outcomes being used to shape future policy recommendations.

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2022 CDC Draft Revision of the Opioid Prescribing Guidelines

- The Opioid Prescribing Guideline update is based on 5 systematic reviews of the best available evidence. The draft was reviewed by an Independent Federal Advisory Committee (CDC's Board of Scientific Advisors for the National Center for Injury Prevention and Control). However, the CDC states the names of the individuals on the Opioid Work-Group will be withheld from the public purview until the final version of the guidelines are published. This is extremely concerning given the immense impact these guidelines will have on the public's health and well-being. The CDC must provide the full names of all individuals associated with this revision prior to its publication.

- The revised guidelines expand the application of the Guidelines from previously applying to just Primary Care Providers to now applying to all other specialties providing outpatient opioid prescriptions. (including acute pain, sub-acute pain and chronic pain)

- The authors failed to to acknowledge the patient suicides that resulted from the restrictive opioid policies that came from the 2016 Opioid Prescribing Guidelines.

- The draft guidelines are under the peer review process. However, once again, the CDC is refusing to provide the names of the individuals engaged in the peer review process until the final revision is published. This is highly questionable of the CDC and creates serious with concerns regarding conflicts of interest among the members of the Opioid Workgroup.

- The authors acknowledge that evidence of the effects of combination therapy versus opioid or non-opioids **is lacking**. Yet, despite this admitted fact, the authors continuously recommend the use of non-opioid and non-pharmacological treatments to be given as the primary treatment for acute, sub-acute and chronic pain care.

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2022 CDC Draft Revision of the Opioid Prescribing Guidelines

- The author's of the report state for providers to refer to a separate post-surgical guideline for opioid dosing based on surgical procedure. However, this so-called guideline, is a singular publication by a private entity called Michigan OPEN. This is problematic because they (Michigan OPEN) conducted their own private research and created arbitrarily quantity caps on prescription opioids for the treatment of postoperative pain. There are a number of concerns regarding how this entity came up with their recommendations. A **singular private corporation** should not have the **sole power** to determine post-operative care for the entire population. Their research is **limited** and has not been widely verified by independent research.

- When the authors are not referencing their own work, they make bold, authoritative statements regarding the evidence-base and other researach outcomes without providing the necessary citations. This is highly problematic as they appear to be using one-off studies to justify massive changes in the management of pain in the nation; oftentimes, in a manner that would benefit them personally/financially.

- The authors reference "one cohort study" (that) found long-term opioid therapy was not associated with improved pain, function, or other outcomes versus non-opioids. However, the authors admitted earlier in the report that long-term studies were **excluded** from the review. This leaves us with serious questions about the validity of this statement. Did the Systematic Evidence Review by AHRQ include long-term studies or not? The authors appear to blatantly contradict themselves with this statement.

- The authors also cited "a short term study, there was no difference between opioids and nonopioids in short-term pain, function, health status/quality of life." Yet, in another section of the draft 2022 Opioid Prescribing Guidelines, they clearly state that **no studies** on the difference between opioid and non-opioid medications have been completed.

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2022 CDC Draft Revision of the Opioid Prescribing Guidelines

- The authors acknowledge that the evidence used to create their recommendations on opioid tapering was **limited to 1 trial**. This begs the question, why would the committee limit the data-set to a singular study? The committee also **fails to identify which study was used** for the basis of their recommendations. Despite the severe limitations of the data regarding the tapering of patients off opioid based medications, the authors dedicate the majority of the 2022 Opioid Prescribing Guidelines to this topic. Additionally, the authors continuous use of their own research throughout the report lends concerns to whether or not the "one study" used is also their own work. The CDC needs to provide the pubic a citation for the study used to create these recommendations given their serious impact on the public's health and well-being.

- The authors attempt to create individualized guidance for a variety of painful conditions. Yet, upon review of the recommendations made, the authors take the same generalist approach towards all conditions with a focus on the use of non-opioid and non-pharmacological treatments instead of opioid-based medications. Oftentimes making unproven and/or contradictory statements about their efficacy.

    * Exercise
    * Cognitive Behavior Health
    * Mind-Body Practices
    * Multi-disciplinary Rehabilitation
    * Acupuncture
    * Spinal Manipulation
    * Massage
    * Yoga
    * Anticonvulsants
    * Antidepressants
    ** NSAIDS

**The author's acknowledge the serious harms associated with NSAID however repeatedly recommend their use throughout the draft.

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2022 CDC Draft Revision of the Opioid Prescribing Guidelines

- The authors acknowledge there is a lack of data on the harms of non-pharmacological therapies. Yet, despite this admittance, they repeatedly made ascertains that "there is no evidence of harms." Once again we see the authors contradicting themselves and inserting their personal opinions (bias) instead. The authors have no right to make claims of "no evidence of harms" when there have not been **any studies** on the outcomes. As a patient and an advocate, we come across people every day who have experienced great harms from a number of non-opioid and/or non-pharmacological modalities. CIAAG is working with our federal representatives on an initiative to get Congressional funding allocated to perform these much needed studies. The authors repeat this behavior (on page 52) claiming "*across all classes of non-opioid therapies that the incidence of serious adverse events was low*." Yet, in the second half of their statement, they acknowledge "*however, the trials were not designed to assess serious adverse events and that there were a few serious adverse events*", thereby contradicting themselves multiple times in a single sentence. (They repeated this misleading claim again on page 55).

- The author's acknowledge:

    - Evidence is stronger for the use of pharmacological over non-pharmacological therapies.
    - The results of postoperative pain were based on a **small number of trials** and pain related to a **limited set of surgical procedures**. Again, we see the authors use of "one-off, small studies" to justify massive public-health changes for society.
    - Evidence for non-pharmacological therapies for acute pain was **limited**. Yet despite this acknowledgement, the authors made a number of recommendations for patients to pursue these modalities in treating several common pain conditions.
    - There is **limited** evidence on the benefits and harms of opioids.

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2022 CDC Draft Revision of the Opioid Prescribing Guidelines

- The authors claim, "opioids were associated with increased risk of adverse events" yet, in the same sentence they continue to acknowledge, "evidence on serious adverse events was lacking." This is an example of what we see throughout the report; the authors will acknowledge a lack of evidence exists, then follow up that statement by saying the evidence does exist thus leaving the reader in a position to question the validity of the entire statement. It is accurate to state, assertions made in a guidance document that will be used to guide patient care decisions should not and cannot be made without sufficient supporting evidence (which the authors acknowledge they do not have). It is also accurate to state that these unproven statements are ambiguous and speculative in nature and therefore, should not be included within the report as it may lead readers to cultivate false beliefs about the management of pain.

- The authors cite the results of a survey showing "high support for exercise and/or complementary medicine therapies and psychological therapies." While some patients may believe they have preferences in their future treatments, the results of this survey are **not reflective** of the true patient population. Many patients may find these ideals acceptable, resulting from pressure to conform to what has been deemed "socially acceptable"; however, in the face of serious pain and illness, these same individuals could very likely change their views on what they perceive to be a "preferred" treatment. There are multiple examples of irrelevant opinion based surveys used by the authors as supporting rational for their recommendations.

- While the authors claims not to support or encourage the use of a step-therapy approach to pain management, it is clear that the application the recommendations being made do effectively put patients through a step-therapy process in managing their pain and accessing certain modalities. When we use the step-therapy approach to managing illness/injury/pain we risk leaving patients in limbo with woefully inadequate pain care while enduring severe, inhumane suffering as they try and fail different steps.

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2022 CDC Draft Revision of the Opioid Prescribing Guidelines

- Throughout the report, the authors make strong statements regarding opioid and non-opioid therapies yet fail to include the appropriate citations to provide their assertions. Given the continuous conflicting statements throughout the report, it is vital the finalized publication of the 2022 Opioid Prescribing Guidelines include all relevant citations to allow for public review and assessment of potential conflicts of interest and/or personal biases in the research used.

- The authors ask for "*special attention to ensure the guidelines are not misapplied*." While this appears to be a positive step by the CDC, the application of the guidelines will be entirely dependent upon the training promoted by the CDC and other inter-agency work being conducted. It is the responsibility of CDC to ensure proper **interagency coordination** is accomplished to provide national education and keep providers updated on the current day guidance and application within their clinics. The CDC's ascertain the previous Opioid Guidelines were misapplication are no more than a deflection of the CDC's failure to provide balanced, patient-centered education through Medical Conferences and other training opportunities.

- They authors claim "non-opioids are effective for many types of acute pain." This is a broad statement and is dependent upon a number of factors. However, it should be noted that a number of the non-opioid based treatments available do not begin to provide pain relief for ***nearly 30 days***. The author's must ensure proper guidance for this period of time is provided in the final publication to ensure these patients are not left suffering for a prolonged period of time while they wait for the medications to become effective.

- They authors acknowledge there have been no studies on the cost-effectiveness of opioids versus no-opioid or non-opioid therapy. Yet, further into the report the authors make assertions about the cost-effectiveness of non-pharmacological and non-opioid therapies. Once again, providing conflicting statements as their rationale for the recommendations contained within the draft report.

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2022 CDC Draft Revision of the Opioid Prescribing Guidelines

- Throughout the report, the authors make statements claiming non-opioid medication should be used over opioids. However, the author's also made it clear that the research **is limited or completely lacking**. It is highly unethical to create national guidelines for the entire citizenry **before having the appropriate reserach to prove its efficacy**. This is repeated throughout the entire draft report with non-opioid and non-pharmacological modalities becoming the primary treatment method for the majority of pain conditions despite lack of evidence.

- Despite the massive lack of evidence (for non-opioid and non-pharmacological treatments) the authors make it clear, they are recommending the implementation of non-opioid and non-pharmacological treatments to be the primary focus in the treatment of pain. It is important to note, the recommendations being made by the authors of the 2022 Opioid Prescribing Guidelines directly support the ideals published in the HHS Pain Management Task Force Report in 2019. The author's even go as far as to ask for insurers to expand coverage and access in these areas to support their "implementation." It is important to note, the many of the modalities being recommended by the 2022 Opioid Prescribing Guidelines are the same modalities the HHS Pain Management Task Force Report was requested to have "more research" conducted in order to fill current research gaps and/or inconsistencies.

- The 2016 Opioid Prescribing Guideline dose limitation of 90 MME was not referenced in the draft; however, the draft 2022 Opioid Prescribing Guidelines "caution" against the use of opioids in excess of 50 MME's. Effectively reducing the maximum daily dose recommendation nearly an **additional 50%**. The authors simply "softened" the language used to present the recommendation. Yet, the recommendation still stands and is greatly reducing daily maximum dosing even further despite the widespread harms from the original guidance.

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2022 CDC Draft Revision of the Opioid Prescribing Guidelines

- The revised recommendations promote the use of "mindfullness" as treatment of biomedical conditions. While coping skills can be helpful for many people, it should never supplement biomedical healthcare. Individuals involved in the 2022 Opioid Guidelines have a vested financial and personal interest in promoting these ideals. For example, Beth Darnall, PhD, is the Principal Investigator on the EMPOWER Study and VALUE Study which are designed support (her theory) that people can self manage pain with a simple 2 hours class she hosts on zoom. This type of narrative is abusive towards people in pain and equates to medical conversion therapy where people with serious illnesses are gaslit by people in positions of power who tell them, "they are not feeling what they think they are." CIAAG strongly opposes the use of unproven physiological theories to dismiss patient bio-medical needs.

- The revised version of the Opioid Prescribing Guidelines recommends against the use of opioids in persons over 65yrs old. The authors should not be providing any guidance that outright denies an entire class of citizens access to medication. Instead the author's should be recommending "caution" in this community rather than outright recommending this entire population be denied access to vital medications. This recommendation is a direct violation of a patient's right to receive individualized care. The care they receive should be dictated by their unique situation, not by recommending a blanket removal upon reaching a certain age. In addition, this recommendation fails to address patients **already on opioid medications** and sets the stage for them to be forcibly removed from their pain medications upon their 65th birthday for no other reason than their age.

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2022 CDC Draft Revision of the Opioid Prescribing Guidelines

- The authors cite the **SPACE Trail** multiple-times as supporting evidence that NSAIDS are equally effective as opioid analgesics in relieving pain. However, upon close examination of the study there are several disconcerting factors that raise questions about the validity of the outcomes.

1. The painful conditions these patients suffered from were limited to chronic back pain and osteoarthritis of the knee and/or hip. (It is worthy to note that typically, the first-line therapy for osteoarthritis is NSAIDS).
2. The group of study participants are hardly representative of the general patient population (e.i. 240 patients from the V.A. of which 87% were male). Despite this limitation the study results were generalized and applied to a wide-range of illnesses/conditions.
3. Excluded were patients who were already on long term opioid therapy which presents the possibility that the study excluded individuals who have tried and failed alternative means of pain control.
4. Concerns of selection bias in the participants.
5. The study was conducted via a questionnaire which opens up concerns due to the known lack of reliability in self reporting.
6. The patients were studied over a 12 month period; their pain intensity and related function levels measured at the beginning of the study and then again at 12 months via the use of a questionnaire. It was during this 12 month time period that the study protocol **underwent a total of 8 changes**. Initial recorded pain levels from the patients were mid-range/moderate which indicates that the study **did not capture** the experiences of those who suffer severe pain.
7. Soon after the study's publication, misleading media framing ensued with the use of attention grabbing headlines that read, *"Opioids don't treat chronic pain any better than ibuprofen*" and "*Opioids no better than common painkillers for treating chronic pain.*" These headlines (misinformation) sadly worked to lend credence to the claim that "*opioids are lousy drugs for chronic pain*"; a favorite statement that anti-opioid activists use to further their agenda. This amounts to nothing more than propaganda and it has led to a deepening of society's misunderstanding about opioids for chronic pain as well as furthering the stigmatization of the patients that necessitate their use in order to maintain a reasonable level of function and quality of life.

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2022 CDC Draft Revision of the Opioid Prescribing Guidelines

The overarching theme throughout the report was the use of the author's personal research studies and one-off (often bias) studies to justify massive systematic policy changes surrounding pain management in the nation. In implementation the revised policy guidance **will result** in the implementation of a step-therapy approach towards the management of pain based on deeply flawed **medical theories**.

Additionally, the 2022 Opioid Prescribing Guidelines have expanded their scope from opioids only to becoming a guidance document on the appropriate treatment of pain itself.

Most disconcerting is the recommendations made by the authors will result in patients being provided suboptimal care via the use of (often-untested) treatment modalities in an attempt to avoid initiating opioid based medications.