January 13, 2016

National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
4770 Buford Highway NE
Mailstop F-63
Atlanta, GA 30341

Re: CDC-2015-0112-0001 Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain

To Whom It May Concern:

On behalf of Trust for America's Health (TFAH), I am writing to comment on the Center for Disease Control and Prevention's (CDC) proposed 2016 Guideline for Prescribing Opioids for Chronic Pain. TFAH is a nonprofit, nonpartisan organization dedicated to improving population health through disease prevention and health promotion. Thank you for providing the opportunity to comment on these guidelines, which will have a significant impact on the nation's efforts to address opioid misuse and on the treatment of patients suffering from chronic pain who depend on access to opioids. It is essential that the medical needs of both patient groups are taken into consideration in the development of prescribing guidelines.

We commend the CDC for its work in addressing the opioid epidemic and support the effort to craft prescribing guidelines. The misuse and abuse of prescription drugs, including opioids, and the corresponding injuries and deaths, constitute a growing public health crisis. In TFAH's June 2015 report, *The Facts Hurt: a State by State Injury Prevention Policy Report*, we noted that drug overdoses became the leading cause of injury death in the United States in 2013, causing almost 44,000 deaths.[1] Approximately 6.1 million Americans abuse or misuse prescription drugs, and more than 60 Americans die every day from a prescription drug overdose. Overdose deaths involving prescription painkillers have quadrupled since 1999 and now outnumber deaths from all illicit drugs, including heroin and cocaine, combined.

In another TFAH report, *Prescription Drug Abuse: Strategies to Address the Epidemic* we recommended, among a range of other steps, that "all providers should receive education and continued training about appropriate prescribing of commonly abused medications."[2] In preparation for that report, TFAH worked with a range of partners and experts to identify promising policies and approaches to reducing prescription drug abuse in America.[3] Among

[1] Trust for America's Health, *The Facts Hurt: A State-by-State Injury Prevention Policy Report 2015* (2015) (available at http://healthyamericans.org/assets/files/TFAH-2015-InjuryRpt-final6.18.pdf).

[2] TFAH, *Prescription Drug Abuse: Strategies to Stop the Epidemic* (2013) (available at healthyamericans.org/assets/files/TFAH2013RxDrugAbuseRpt16.pdf).

[3] *Id.*

these approaches is an effort to ensure responsible prescribing practices from every medical professional licensed to prescribe opioids. This includes increasing education of healthcare providers and prescribers to better understand how medications can be misused and to identify the signs of addiction so patients who need treatment can be referred for it.[4]

TFAH supports CDC's efforts to address opioid misuse and reduce overdose deaths, including efforts in the area of provider education and the development of these Guidelines. As CDC has noted, higher prescribing of opioids is associated with more overdose deaths. However we also recognize the consequences of inadequate or under treatment of pain for certain patients and are concerned about unintended consequences that could result if opioids are restricted in a manner which impedes the ability of patients with chronic pain to access needed medications.

We thank the CDC for making clear that this Guideline does not apply to patients in active cancer treatment, palliative care and end-of-life care. We encourage the CDC to also acknowledge within the Guidelines that there is a need for chronic pain care which at times requires the use of opioids. Complex chronic diseases like chronic pain require comprehensive, individualized approaches which may or may not include prescription medications. In every treatment plan, consideration of adding any medical therapy (pharmacological or otherwise) should always include a risk benefit analysis. A plan of care should only include those therapies for which potential benefits outweigh risks, based on the judgment of the physician and the patient in collaborative, shared decision-making.

At the most direct level, restrictions on access to pain medicine could increase the number of people living with chronic pain. The National Institutes of Health Final Report on the "The Role of Opioids in the Treatment of Chronic Pain" workshop noted that chronic pain affects as many as 100 million Americans.[5] Multiple studies have found that people living with chronic pain experience higher rates of suicidal thoughts, attempts, and completions.[6] Issuing guidelines without corresponding resources for increased research on and access to comprehensive pain management services could leave millions of people in increased pain.

We urge CDC to refine its Guideline in a number of areas to maintain access to vital pain treatment for patients in need. Our specific comments are below.

- **It is important that the evidence-base related to the role of opioid therapy in the treatment of chronic pain continues to grow.**

  As noted above, 100 million Americans suffer from chronic pain. As the Guidelines acknowledge, there is little high quality evidence on the role of opioids in treating

[4] *Id.*

[5] National Institutes of Health, "Final Report: The Role of Opioids in the Treatment of Chronic Pain" (Sep. 2104) (available at https://prevention.nih.gov/docs/programs/p2p/ODPPainPanelStatementFinal_10-02-14.pdf).

[6] Smith et al., "Suicidal ideation, plans, and attempts in chronic pain patients: factors associated with increased risk" *Pain* Volume 111(1-2), September 2004, p 201–208.

chronic pain. The consequences of inadequate treatment of pain can be severe, and we must ensure that responses to the opioid epidemic do not have unintended consequences of depriving patients from needed treatment options. We urge CDC to balance carefully the needs of some pain patients with efforts to promote appropriate prescribing, reduce misuse and expand access to treatment for individuals with substance use disorder. We also urge the CDC to continue to engage with other federal, private sector research organizations, and other recognized experts in the field to rapidly build out the knowledge base surrounding appropriate opioid use, alternatives to opioids, and the most effective prescribing practices.

- **Clarify that patients need not demonstrate improvement in <u>both</u> pain <u>and</u> function in order to continue receiving opioid therapy. (Recommendations 1 and 2)**

  We believe that there are clinical circumstances in which achieving stability of pain OR stability of function may be an appropriate goal of treatment. Recommendation 1 currently reads in part, "Providers should only consider adding opioid therapy if expected benefits for both pain *and* function are anticipated to outweigh risks to the patient" (emphasis added). We recommend replacing this text with, "<u>Providers should only consider adding opioid therapy if doing so increases the likelihood of achieving mutually pre-determined goals of care</u>."

  Similarly, though the narrative in Recommendation 2 acknowledges that "there are some clinical circumstances under which reductions in pain without improvement in function might be a more realistic goal," the recommendation itself states, "Providers should continue opioid therapy only if there is clinically meaningful improvement in pain *and* function that outweighs risk to patient safety" (emphasis added). We suggest that this sentence be rewritten as follows: "<u>Providers should continue opioid therapy only if there is clinically meaningful progress toward achieving the mutually pre-determined goals of care</u>."

  Furthermore, many insurers don't adequately cover or reimburse for non-pharmacologic therapies such as acupuncture, biofeedback, relaxation, and other interactive, multimodal therapies. Payer policies—both public and private—would need to be fundamentally changed to support this recommendation. Better evidence is needed to inform policy-making in this area.

- **Discussion of Risks and Benefits**. **(Recommendation 3)**

  We support Recommendation 3 and agree that providers should discuss with patients known risks and benefits of opioid therapy and patient and provider responsibilities for managing therapy.

- **Prescribe immediate release instead of extended release/long-acting opioids. (Recommendation 4)**

  We support this recommendation.

- **Eliminate recommended maximum dose of 90 MME/day. (Recommendation 5)**

  We agree that starting with the lowest effective dose is appropriate. This philosophy applies to all pharmacologic therapy, for chronic pain or any condition. We also agree that caution should be exercised at all doses and that additional precautions should be implemented and strengthened as doses increase. We are less certain about setting a specific threshold for that action, but we do not see a >50 MME/day threshold as unreasonable in that context.

  However, we have concerns about setting a maximum recommended dosage level. We note that this recommendation conflicts with approved product labeling for the clinical use of opioid analgesics and the findings of a recent review by the Food and Drug Administration. Furthermore, suggesting that providers "generally" avoid increasing dosage to >90 MME/day could result in unintended consequences that may prevent providers from prescribing doses at a higher level, even when clinically indicated. In addition, it is possible that policymakers may interpret this dosage recommendation (and perhaps codify it into law) as a legally binding ceiling. Further, commercial health plans and other payers like Medicare may interpret this to be a ceiling dosage level and set reimbursement and other policy around the level.

  We urge CDC to eliminate the 90 MME/day reference and instead insert the following: "Providers should use caution when prescribing opioids at any dosage, and should implement additional precautions when increasing dosage to >50 morphine milligram equivalents (MME)/day. Dose increases should be considered only when the patient is making clinically meaningful progress toward the mutually-determined goals of care, and when a further dose increase is expected to sustain that progress."

- **Eliminate the following sentence "Three or fewer days usually will be sufficient for most nontraumatic pain not related to major surgery." (Recommendation 6)**

  We have no objection to the first two sentences of Recommendation 6, but suggest the third sentence be deleted. Pain is an intensely personal experience influenced by a number of factors. Patient reported intensity of pain may not correlate with the magnitude of injury. Even minor surgeries can produce extensive pain for more than three days. Again, we are concerned about setting an arbitrary, bright-line limit that could result in unintended consequences. States could codify this limit, creating difficulties for individuals with acute pain for whom a 3-day supply is insufficient. Suggesting a short time limit could require individuals to get multiple prescriptions from their provider, adding time, effort and cost burdens for the patient (e.g. additional co-pays for a new office visit) and could potentially increase health inequities.

- **Specify that "Providers should offer a prescription of naloxone to every patient prescribed an opioid." (Recommendation 8)**

We support this recommendation, but believe it should be stronger in encouraging providers to offer a prescription for naloxone to every patient who is prescribed an opioid. This prescription should be offered in the context of a thorough discussion of the risk of respiratory depression and factors that might affect that risk. That discussion should include reminding the patient of the risk associated with other people, besides the patient, accessing opioids that are not stored securely, as well as information on safe disposal of unused medication.

Naloxone can be used to counter the effects of an opioid overdose. Administration of naloxone counteracts life-threatening depression of the central nervous system and respiratory system, allowing an overdose victim to breathe normally. Although naloxone is a prescription drug, it is not a controlled substance and has no abuse potential. Furthermore, it can be administered by minimally trained laypeople. A CDC *Morbidity and Mortality Weekly Report* study of 188 local naloxone distribution programs found that more than 10,000 overdose reversals were reported.[7]

Expanding access to naloxone has been supported by the U.S. Conference of Mayors (2008 resolution), the American Medical Association (2012 resolution), the American Public Health Association and a range of public health, law enforcement and other organizations. In a survey of states' naloxone and "Good Samaritan" laws conducted by the Network for Public Health Law, the group concluded that, "it is reasonable to believe that laws that encourage the prescription and use of naloxone and the timely seeking of emergency medical assistance will have the intended effect of reducing opioid overdose deaths," and found "such laws have few if any foreseeable negative effects, can be implemented at little or no cost, and will likely save both lives and resources."[8]

- **Refer patients to substance misuse treatment if prescription drug monitoring program (PDMP) data shows evidence of misuse. (Recommendation 9)**

  We support recommendation 9 regarding provider review of PDMP data, but request that CDC also add text into the actual recommendation that if evidence of opioid misuse exists, the provider should facilitate referral to appropriate treatment and support systems. As discussed in TFAH's 2013 report,[9] strategies such as PDMPs can help healthcare providers and others identify individuals with a substance use issue, but those tactics are

[7] Wheeler et al., "Community-Based Opioid Overdose Prevention Programs Providing Naloxone — United States, 2010" *Morbidity and Mortality Weekly Report* February 17, 2012 / 61(06);101-105 (available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6106a1.htm).

[8] Network for Public Health Law, "Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws" (2014) (available at http://www.networkforphl.org/_asset/qz5pvn/network-naloxone-10-4.pdf).

[9] TFAH, "Prescription Drug Abuse: Strategies to Stop the Epidemic" (2013)(healthyamericans.org/assets/files/TFAH2013RxDrugAbuseRpt16.pdf).

most effective when combined with strategies to connect these individuals to appropriate treatment. Adding similar language in the recommendation will highlight for providers the need to make appropriate referrals (also see our comment below on Recommendation 12).

- **Address access issues and potential stigmatization. (Recommendation 10)**

  According to the American Medical Association, urine drug testing is a risk mitigation strategy that can be helpful in designing treatment and monitoring strategies for patients on chronic opioid therapy. However, significant knowledge gaps exist among providers about the use and interpretation of urine drug testing. In addition, insurance does not always cover routine urine drug testing, and the costs associated with this requirement could be extensive. We are also concerned about the potential for stigmatization of chronic pain patients. We encourage the CDC to build in qualifying statements related to the adequacy of insurance coverage and avoidance of stigmatization.

- **We support Recommendation 12, but believe that CDC needs to work with other federal agencies and stakeholders to reduce barriers to treatment for substance use disorder.**

  We support recommendation 12, as TFAH recognizes that expanded access to substance misuse treatment is an essential part to any effective strategy to prevent and reduce substance misuse. Unfortunately many barriers exist to fully realizing appropriate evidence-based treatment for patients with opioid use disorders, including:

  - The number of providers available to adequately treat patients with opioid disorder is insufficient;
  - While the number of uninsured and underinsured is shrinking due to the Affordable Care Act, many remain with inadequate access to meaningful treatment;
  - Lack of education and training regarding appropriate treatment strategies for substance use disorder;
  - Poor public and private payer policies that do not cover appropriately or fully an array of treatments for patients with opioid disorder.[10]

  To truly address opioid addiction and misuse, CDC needs to work with other federal agencies and stakeholders to continue to reduce these barriers.

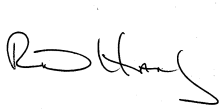
[10] Anna Gorman, "Barriers Remain Despite Health Law's Push To Expand Access To Substance Abuse Treatment" *Kaiser Health News* (Apr. 10, 2014) (available at http://khn.org/news/substance-abuse-treatment-access-health-law/).

Conclusion

Trust for America's Health appreciates the opportunity to review and comment on these important guidelines. We encourage CDC to work with other federal agencies and stakeholders to create a balanced approach that does not impede access to required medications. We support the effort to craft prescribing guidelines and hope the final guidelines will balance the needs of patients at the heart of these two public health crises: misuse and abuse of opioids and chronic pain.

Thank you for your consideration. If you have any questions, please contact Becky Salay, TFAH's Director of Government Relations at (202) 864-5945 or bsalay@tfah.org.

Sincerely,



Richard Hamburg
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