

Annex I: DEA Response



U. S. Department of Justice
Drug Enforcement Administration
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Springfield, Virginia 22152

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SEP 14 2018

Laura Mills
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Human Rights Watch
350 Fifth Avenue, 34th Floor
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Dear Ms. Mills:

Thank you for your letter dated August 28, 2018, requesting information on the Drug Enforcement Administration's (DEA) enforcement actions on the inappropriate prescribing of opioids. We appreciate the opportunity to provide input on the report you reference in your request below. As you know, the Controlled Substances Act (CSA) and its implementing regulations established a closed system of distribution with built-in checks and balances to ensure the appropriate use of controlled substances and to maintain the integrity of the system through an accountability process. One of the most important principles underlying the CSA, and its implementing regulations, is that to be valid, every prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner who is acting in the usual course of his or her professional practice. *United States v. Moore*, 423 U.S. 122 (1975) and 21 C.F.R. § 1306.04(a). There are currently over 1.67 million DEA-registered practitioners who can prescribe controlled substances for their patients.

Federal regulations do not define the term legitimate medical purpose nor do they set forth the standards of medical practice. It is up to each DEA-registered practitioner to treat a patient according to his or her professional medical judgment in accordance with a standard of medical practice that is generally recognized and accepted in the United States. Therefore, as long as practitioners are issuing a prescription for a control substance for a legitimate medical purpose and they are acting in the usual course of professional practice, they are acting within the law. This is the prescribing practitioner's primary responsibility under Federal and State law and regulations.

DEA only investigates and takes appropriate action against practitioners who are not fulfilling their responsibilities under the CSA. DEA has consistently emphasized and supported the prescriptive authority of an individual practitioner under the CSA to administer, dispense, and prescribe controlled substances for the legitimate treatment of pain within acceptable medical standards as outlined in the DEA's policy statement published in the Federal Register (FR) on September 6, 2006, titled, "Dispensing Controlled Substances for the Treatment of Pain." See 71 FR 52716. A copy is enclosed for your convenience.

Although DEA is the agency responsible for administering the CSA, DEA does not act as the federal equivalent of a state medical board overseeing the general practice of medicine and lacks the authority to issue guidelines that constitute advice relating to the general practice of medicine.

These state medical boards regulate the practice of medicine, dentistry, nursing, physician assistants, and veterinary medicine. It should be noted that states are permitted to impose legal requirements beyond what federal law and regulations require.

You also requested answers to some questions which the DEA is not able to publicly provide. If you wish, you may attempt to obtain this data through a FOIA request. Some information that may be of interest to you can be viewed at our web site (www.DEADiversion.usdoj.gov) at the following link:

https://www.DEADiversion.usdoj.gov/crim_admin_actions/index.html

I trust this letter adequately addresses your inquiry. For information regarding the DEA Diversion Control Division, please visit www.DEADiversion.usdoj.gov. If you have any additional questions on this issue, please contact the Diversion Control Division Liaison Section, Chief James Arnold at (202) 353-1414.

Sincerely,



Keith Brown
Deputy Assistant Administrator
Diversion Control Division

Enclosure

Annex II: CDC Response



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

August 28, 2018

Ms. Laura Mills
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New York, NY 10118-3299

Dear Ms. Mills:

Thank you for your letter to the Director of the National Center for Injury Prevention and Control at the Centers for Disease Control and Prevention (CDC) regarding the prescribing of opioid analgesics and chronic pain. We believe that patients with chronic pain deserve safe and effective pain management. Given the opioid overdose epidemic in the country today, our focus is on addressing the needs of patients living with pain while also reducing the risk of opioid use disorder and overdose.

CDC offers health systems and providers tools, recommendations, and guidance for decision-making based on evidence. As you know, the [*CDC Guideline for Prescribing Opioids for Chronic Pain*](#) (Guideline) provides recommendations about the appropriate prescribing of prescription opioids and other treatment options to improve pain management and patient safety.

At CDC's National Center for Injury Prevention and Control (NCIPC), patient safety is our top concern, and the driving factor behind the development of the Guideline. We agree that it is important that patients receive appropriate pain treatment, and that the benefits and risks of treatment options are carefully considered. The Guideline provides guidance on how to do this, and multiple recommendations stress providers working in consultation with their patients to address chronic pain. The Guideline encourages physicians to continue using their clinical judgment and base treatment on what they know about their patients.

In your letter, you presented several questions regarding the Guideline. These questions are answered in the following pages.

1. The CDC guidelines state that “extensive evidence suggests some benefits of nonpharmacologic and nonopioid pharmacologic treatments compared with long-term opioid therapy, with less harm.” Can you confirm which medical literature informed this conclusion?

CDC conducted an extensive review of over 130 of the most relevant and recent scientific studies on the effectiveness and risks of opioids and other pain treatments. This review built on an earlier review conducted by Agency for Healthcare Research and Quality (AHRQ). This body of evidence suggests that nonopioid treatments, including nonopioid medications and nonpharmacological therapies, can provide relief to those suffering from chronic pain—and are safer. This evidence is summarized in the full guideline (<https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>) and the accompanying online evidence reviews (<http://stacks.cdc.gov/view/cdc/38026> and <http://stacks.cdc.gov/view/cdc/38027>).

CDC’s clinical evidence review identified studies examining the effectiveness of long-term opioid therapy and opioid-related harms, such as opioid use disorder and overdose. The review could not identify any studies that examined the effectiveness of long-term opioid therapy for chronic pain with outcomes extending at least 1 year. Most effectiveness trials were 6 weeks in duration or less. These findings supplement a previous review (*American Pain Society–American Academy of Pain Medicine Opioids Guideline Panel. Guideline for the use of chronic opioid therapy in chronic noncancer pain: Evidence review. 2009.*) that showed opioids are moderately effective for pain relief in the short term, with small benefits for functional outcomes, and a high percentage of patients discontinuing opioids because of lack of effectiveness and adverse events. Importantly, in the clinical review conducted for the CDC guideline, several studies highlighted the potential harms of opioids. For example, 11 studies examined abuse, addiction, and related outcomes, showing a range of rates of opioid abuse or dependence diagnoses. In primary care settings, prevalence of opioid dependence (using DSM-IV criteria) ranged from 3% to 26%. Two studies in the clinical review emphasized how higher opioid doses are associated with increased risk for overdose. Additional studies investigating the benefits and harms of opioid therapy were identified in the contextual evidence review of epidemiology research. These studies also indicated that opioid-related overdose is dose-dependent, with higher opioid dosages associated with increased overdose risk.

CDC’s contextual evidence review also identified studies on the effectiveness of nonpharmacologic therapies and nonopioid medications (from 19 sources), and existing guidelines that emphasize their preferred use. Nonpharmacologic therapies and nonopioid medications were found to be effective for managing chronic pain in studies ranging in duration from 2 weeks to 6 months. Nonpharmacologic therapies and nonopioid medications were recommended as first line options in previous guidelines for chronic pain conditions. Some of

these therapies are associated with specific risks, but are generally not associated with drug dependence, and numbers of fatal overdoses associated with the nonopioid medications studied are a fraction of those associated with opioids.

In sum, the guideline recommendations were based on evidence reviews which found that no evidence shows a long-term benefit of opioids, extensive evidence shows the possible harms of opioids (including opioid use disorder and overdose), and extensive evidence suggests benefits of nonpharmacologic therapies and nonopioid medications, with less harm.

Note that results from research published after the CDC Guideline was published are consistent with those cited in our evidence reviews. The first long-term (12 months) randomized trial of opioid vs. non-opioid medications for chronic pain found pain intensity significantly reduced with non-opioids compared with opioids, while adverse effects were more common with opioids. (Krebs EE, Gravelly A, Nugent S et al. Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain: The PACE Randomized Clinical Trial. *JAMA*. 2018 Mar 6;319(9):872-882. doi: 10.1001/jama.2018.0899)

2. **The CDC guidelines recommend that physicians avoid treating patients with doses higher than 90 Morphine Milligram Equivalents (MME). Several studies have indicated that while overdose risk does increase with a higher dose, there is no set threshold at which this risk increases. Why has the CDC selected 90 MME as the threshold dose?**

CDC recommends re-assessing opioid treatment before increasing dosage to 50 MME/day or greater and avoiding or carefully justifying opioid titration to 90 MME/day or greater. These recommendations are intended to be used for initiating patients on opioids. These dosage thresholds for increased caution were determined based on the most recent scientific evidence regarding the association between opioid dosage and overdose risk. This evidence is summarized in the guideline. The evidence reviews identified studies that examined opioid-related harms, such as abuse, addiction, and overdose, and their relation to dosage. Opioid overdose risk increases in a dose-response manner. Dosages of 50–99 MME/day have been found to increase risks for opioid overdose two-fold to five-fold compared with dosages of 1–19 MME/day. Dosages ≥ 100 MME/day increase risks of overdose up to nine times the risk at 1–19 MME/day. Among a national sample of veterans with chronic pain receiving opioid treatment and dying of opioid-related overdose, average prescribed dosage was 98 MME/day (compared with an average dosage of 48 MME/day among patients not experiencing fatal overdose), suggesting the need for caution before dosages approach 100 MME daily. In this study, the risk of overdose death for patients receiving 90 or more MME/day was nearly 10 times the risk for patients receiving 1-20 MME/day.

3. **The CDC guidelines state that physicians should consider tapering patients if “clinically meaningful improvements in pain and function are not sustained” or if patients show signs of adverse events. Are there any circumstances in which CDC believes a physician would be justified involuntarily tapering a low-risk and compliant chronic pain patient who has improved function and reduced pain?**

CDC does not recommend involuntary tapering. Situations in which clinicians should consider working with patients to taper and discontinue opioids include when patients do not experience meaningful improvements in both pain and function, treatment goals are not met, opioids are no longer needed, or if adverse events put a patient at risk. Tapering plans may be individualized based on patient goals and concerns. More rapid tapers might be needed for patient safety under certain circumstances (e.g., for patients who have experienced an overdose on their current dosage). The guideline emphasizes that providers should offer tapering, and that tapering should be conducted with patient agreement. For patients who chose but are unable to taper, clinicians may assess for opioid use disorder and offer opioid agonist therapy if criteria are met.

4. **The CDC guidelines repeatedly state that clinicians should “work with the patient to taper opioids to safer dosages.” Does the CDC recommend tapering for patients who do not show signs of abuse or adverse health effects?**

Patients on long-term, high-dose opioid therapy are exposed to overdose risk. Because of this, the Guideline recommends that clinicians discuss risks with patients, some of whom may not be aware of evidence from more recent studies about risk of overdose with increasing opioid dosages. The Guideline includes guidance for clinicians to work with patients to taper or reduce dosage only when patient harm outweighs patient benefit of opioid therapy. To emphasize the messages in the guideline, we have a fact sheet on assessing benefits and harms of opioid therapy, which you can find at:

www.cdc.gov/drugoverdose/pdf/assessing_benefits_harms_of_opioid_therapy-a.pdf and on tapering, which you can find at:

https://www.cdc.gov/drugoverdose/pdf/Clinical_Pocket_Guide_Tapering-a.pdf.

5. **Does the CDC recommend that physicians taper chronic pain patients without their consent, if the patient receives therapeutic benefits from the medications whereas other medications or interventions have not shown similar benefits and the patient is reluctant to titrate down from a given dose?**

CDC does not recommend that physicians taper opioids for chronic pain without patient consent. The doctor-patient relationship is important. The Guideline therefore aims to help providers and patients—together—assess the benefits and risks of opioid use and address potential harms. In

treating chronic pain, CDC encourages physicians to continue to use their clinical judgment and base their treatment on what they know about their patients, including the use of opioids if they are determined to be the best course of treatment. The Guideline does not support involuntary tapering. Obtaining patient buy-in before tapering is critical to successful dose reduction.

Many providers have not received specific training in pain management, however. Not all primary care providers, for example, receive extensive academic preparation and training in the nuanced and complex issues of pain management, but must make pain treatment decisions. It is important that patients receive appropriate pain treatment, and that the benefits and risks of treatment options are carefully considered. CDC created user-friendly tools and materials to make the Guideline easy for patients and providers to understand and use. For more information, visit our Guideline Resources page (<https://www.cdc.gov/drugoverdose/prescribing/resources.html>) to learn about resources that can help improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain.

6. Has the CDC monitored implementation of its guidelines? If so, how?

It is important for CDC to continue to research how to prevent opioid use disorder and overdose and help inform and improve providers' ability to offer safer, more effective care based on the best available science. As part of that process, CDC is evaluating the uptake, utility, and public health impact of the Guideline and will monitor and assess physician and patient response to the Guideline.

Specifically, CDC is evaluating implementation of the Guideline by providers, health systems, and insurers. As of April 2018, 46 states implemented activities to improve local prescribing practices so that they are in alignment with aspects of the Guideline. Over 1,300 Continuing Education (CE) credits have been earned from the interactive online training series, *Applying CDC's Guideline for Prescribing Opioids*. Over 3,600 CE credits have been earned from the Clinician Outreach and Communication Activity webinar series. More than 12,000 CE credits were earned during the first year of the Medscape/ *MMWR* continuing education (CE) activity, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016* (<https://www.medscape.org/viewarticle/881589>). This includes 6,816 credits for physicians and 5,151 credits for nurses. Pharmacists and medical students also earned CE credits.

At least 35 state Medicaid programs have elected or plan to implement the Guideline's recommendations. Providers have downloaded over 2,200 copies of the poster *Safer More Effective Pain Management*, 9,800 copies of the *Pocket Guide on Tapering Opioids for Chronic Pain*, and 30,000 instances of the *CDC Guideline Mobile App*. Findings will be released early this fall on how opioid prescribing practices in America have changed since the Guideline

release. Evaluation of national prescribing data from retail pharmacies shows declining rates of average dosage, high dosage prescriptions, concurrent benzodiazepine prescriptions, and overall opioid prescriptions since March 2016. Prescribers are working to provide the safest care for their patients experiencing pain by continuing to change their opioid prescribing practices. This trend illustrates how the availability of an evidence-based clinical practice guideline does help improve the way opioids are being prescribed.

Further, to examine implementation of the Guideline's recommendations directly in health systems, CDC is sponsoring a clinical Quality Improvement Initiative to help health systems integrate recommendations into practice. Within this Initiative, Coordinated Care Plans are encouraged to focus on safer care for patients already on long-term opioid therapy. These activities are being piloted and evaluated in multiple intervention sites. Findings are forthcoming.

7. Has CDC taken any steps to ensure that its recommendations are not implemented in a way that may harm patients? If so, how?

CDC has worked with partners and insurers to communicate the intent and content of the Guideline and to ensure that the recommendations are implemented as intended. For example, CDC worked with CMS to provide content and interpretation of the Guideline's recommendation on increasing opioid dosages. CDC emphasized that this recommendation statement applied to prevention of escalating dosages among patients not already receiving long-term, high-dose opioid therapy, and that different guidance was provided in the Guideline for patients already receiving high-dose opioid therapy. Consideration of this information is recognized in the CMS 2019 Medicare call letter (<https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf>) on pages 246-7. In another instance, after CDC became aware of cases in which buprenorphine treatment for opioid use disorder was denied for insurance coverage based on a misinterpretation of dosage guidance in CDC's Guideline, CDC developed messages and worked with the American Society of Addiction Medicine to make it clear that the dosage thresholds for caution were not intended to apply to medication-assisted treatment for opioid use disorder (see [https://www.asam.org/docs/default-source/advocacy/letters-and-comments/2018-1-4-letter-on-buprenorphine-and-cdcs-guideline-\(002\).pdf?sfvrsn=7fa840c2_2](https://www.asam.org/docs/default-source/advocacy/letters-and-comments/2018-1-4-letter-on-buprenorphine-and-cdcs-guideline-(002).pdf?sfvrsn=7fa840c2_2) and https://www.asam.org/docs/default-source/public-policy-statements/2016-statement-on-morphine-equivalent-units-morphine-milligram-equivalents.pdf?sfvrsn=3bc177c2_6).

CDC developed a series of resources to emphasize the key components of the Guideline, help improve communication between providers and patients, and improve the safety and effectiveness of treatment. Resources include clinical tools (such as a prescribing checklist and tapering pocket guide), posters, videos, training, and a mobile app. Such resources can assist with implementation of the recommendations in the way in which CDC intended. CDC has also

leveraged opportunities to communicate more broadly about the importance of patient safety in tapering and discontinuing opioids, such as in a commentary about *Changing the Conversation about Opioid Tapering*. This commentary in the *Annals of Internal Medicine* (<http://annals.org/aim/fullarticle/2643843/changing-conversation-about-opioid-tapering>) emphasized that CDC's Guideline does not provide support for involuntary or precipitous tapering, and that such practice can be associated with withdrawal symptoms, damage to the clinician-patient relationship, and patients obtaining opioids from other sources. It also emphasized that clinicians have a responsibility to carefully manage opioid therapy and not abandon patients in chronic pain, and that obtaining patient buy-in before tapering is critical. CDC is also in close connection with state health departments to facilitate implementation of the Guideline recommendations as intended through its state programs, such as through the *Prevention for States* program and the *Data Driven Prevention Initiative* (<https://www.cdc.gov/drugoverdose/states/index.html>).

8. **The guidelines' recommendations are not binding on physicians who retain the discretion to make informed clinical decisions about the care for their patients. Is the CDC aware that in multiple states, its recommendations have been written into law and/or used by insurers, state medical boards, and other enforcement bodies as a mandate for physicians? Does the CDC believe that this is appropriate? If not, what steps has it taken to ensure physicians are not unduly limited in their clinical decision making?**

CDC issued a guideline because clinicians and patients were in need of evidence-based guidance to determine when benefits of opioids are likely or unlikely to outweigh their risks, and to determine how to ensure safer and more effective use when opioids are needed. CDC determined that a guideline, which does not restrict providers' ability to prescribe opioids and encourages providers to determine with their patients when benefits of opioids outweigh risks, was the most appropriate means to provide this communication and guidance. The recommendations in the Guideline are voluntary rather than prescriptive standards.

9. **How many communications (for example by email, letter, fax, or other forms of address) has the CDC received from chronic pain patients unable to obtain appropriate medication? What is the CDC's response to such patients?**

Between March 2016 and March 2018, the NCIPC communications office received a total of 769 Guideline-related inquiries. This does not include inquiries that were received by other sources. Of the inquiries received by the NCIPC communications office, 653 included general concerns around the Guideline, the majority from patients and their family members. CDC takes these concerns seriously, and believes that patients with chronic pain deserve safe and effective pain management. Given the opioid epidemic in the country today, our focus is on addressing the

needs of patients living with chronic pain while also reducing the risk of opioid use disorder and overdose. It is the ultimate goal of the Guideline to ensure people who need opioids have access to them, while reducing opioid related deaths. CDC is using the best available research we have today to support providers in relieving patients' pain, preventing patients' suffering, and prolonging patients' lives.

10. How many communications (for example by email, letter, fax, or other forms of address) has the CDC received from physicians who believe the CDC guidelines have been a barrier to appropriate opioid prescribing? What is the CDC's response to such physicians?

As noted in the response to question 9, the NCIPC communications office received a total of 769 Guideline-related inquiries. While most of these were from patients and family members expressing their concerns around the Guideline, CDC does receive periodic communications from physicians.

The Guideline is a set of voluntary recommendations intended to guide primary care providers as they work in consultation with their patients and specialists to address chronic pain. It is not intended to take away physician discretion and decision-making. The Guideline is designed to help physicians assess how to safely maintain or discontinue opioid use in patients who are currently on an opioid treatment plan or start opioids safely if necessary. CDC encourages physicians to continue to use their clinical judgment and base their treatment on what they know about their patients, including the use of opioids if they are determined to be the best course of treatment.

11. In a March article in *The American Journal of Public Health*, four CDC officials wrote that overdose deaths contributable to prescription opioids were likely inflated, due to inclusion of synthetic opioids in that category. Can the CDC state:

a. To what extent do prescription painkillers contribute to the overdose epidemic today? From 1999 to 2016, more than 200,000 people died in the U.S. from overdoses related to prescription opioids. Overdose deaths involving prescription opioids were five times higher in 2016 than 1999. More than 40% of all U.S. opioid overdose deaths in 2016 involved a prescription opioid, with more than 46 people dying every day from overdoses involving prescription opioids. In addition, many overdose deaths related to illicit opioids (heroin and illicitly manufactured fentanyl) occur in people who were exposed to and struggled with prescription opioids before using illicit opioids. Although the proportion of overdose deaths directly attributable to prescription opioids is changing, a majority (67%) of people who enter treatment for opioid use disorder state that they first struggled with prescription opioids, based on the most recent data. (See Cicero TJ, Ellis MS, Kasper ZA. *Addict Behav.* Increased use of

heroin as an initiating opioid of abuse. 2017 Nov;74:63-66. doi: 10.1016/j.addbeh.2017.05.030. Epub 2017 May 23.)

b. Does the CDC have any data as to whether those individuals whose deaths were attributed to prescription opioids had a prescription at that time?

CDC has identified multiple studies that have examined the extent to which prescription opioid-related overdose decedents have had a prescription near the time of their death. For example,

- In a study in West Virginia of prescription opioid-involved overdose deaths, a significant proportion had evidence of a prescription within 30 days of death (87.5% of methadone deaths, 62.5% of hydrocodone deaths, 75.7% of oxycodone deaths (Paulozzi et al. A comparison of drug overdose deaths involving methadone and other opioid analgesics in West Virginia. *Addiction* 2009;104:1541-1548).
- In a study within the Veterans Health Administration, of the 1,136 individuals who died of a prescription opioid overdose during fiscal years 2004 to 2008 in the population studied, 752 (66%) were treated with prescription opioids for pain during those same years (Bohnert et al. Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA* 2011;305:1315-1321).
- In a study of prescription opioid overdose decedents in Utah, in the year prior to death 87.4% were prescribed a pain medication (Johnson et al. Unintentional prescription opioid-related overdose deaths: Description of decedents by next of kin or best contact, Utah, 2008-2009. *Journal of General Internal Medicine* 2013;28:522-529).
- In a study of opioid overdose deaths in West Virginia, of 275 deaths involving prescription opioids, 44.4% had evidence of prescription for all the opioids identified in their body at the time of death. Among those involving Schedule II opioids, 29.1% had prescriptions dispensed within 30 days of death (Hall et al. Patterns of abuse among unintentional pharmaceutical overdose fatalities. *JAMA* 2008;300:2613-2620).
- From 2013 to 2016 in Tennessee, out of 2,594 people dying of prescription opioid overdose, 1,839 (71%) had a record of at least one opioid prescription in the state of Tennessee in the year prior to death. There were a median of 12 opioid prescriptions in that year for each person who had at least 1 opioid prescription. (Nechuta SJ et al. Sociodemographic factors, prescription history and opioid overdose deaths: a statewide analysis using linked PDMP and mortality data. *Drug Alcohol Depend*. 2018 Sep 1;190:62-71. doi: 10.1016/j.drugalcdep.2018.05.004. Epub 2018 Jun 13.)

12. What evidence does the CDC have that the 2016 guidelines have contributed to curbing the opioid epidemic or not?

Findings will be released early this fall on how opioid prescribing practices in America have changed since the Guideline release. Evaluation of national prescribing data from retail pharmacies shows declining rates of average dosage, high dosage prescriptions, concurrent

benzodiazepine prescriptions, and overall opioid prescriptions since March 2016. Prescribers are working to provide the safest care for their patients experiencing pain by continuing to change their opioid prescribing practices. This trend illustrates how the availability of an evidence-based clinical practice guideline does help improve the way opioids are being prescribed.

Thank you, again, for sharing our interest in this important public health issue and for taking the time to correspond with our agency. CDC and our partners will continue to work to identify effective interventions for reducing opioid use disorder and overdose so that people who experience chronic pain can have access to appropriate treatments for their pain. CDC is committed to an approach that protects and prevents opioid overdose deaths, while providing safe, effective pain treatment to patients.

Sincerely,

National Center for Injury Prevention and Control
Centers for Disease Control and Prevention