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August 28, 2019

Uttam Dhillon
Acting Administrator
United States Drug Enforcement Administration
U.S. Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

Dear Acting Administrator Dhillon,

Over the last 20 years, the scourge of the opioid crisis has escalated. Opioid deaths have increased dramatically, accounting for over 47,000 deaths in the United States in 2017.[1] The total economic burden of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.[2]

I commend the Drug Enforcement Administration (DEA) Diversion Control division in actively engaging the 1.6 million DEA registrants involved in all aspects of the opioid crisis including the manufacturing, wholesale production, prescribing, and dispensing of Controlled Prescription Drugs (CPDs), addiction and overdose deaths. The DEA's Diversion Control efforts are geared towards preventing the non-medical abuse of CPDs by providing education and training within the pharmaceutical and medical community and to pursue those practitioners who are operating outside of reasonable medical standards.[3]

As a physician, I know that when the DEA speaks, doctors listen. On April 24, 2019, the Centers for Disease Control and Prevention (CDC) emphasized in a commentary published in the *New England Journal of Medicine* that the 2016 Guidelines for Prescribing Opioids for Chronic Pain have been misinterpreted or misapplied, presenting a challenge to patients with chronic pain and those who treat them.[4, 5] There are anecdotes of patients on stable doses of opioids for years,

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[1] National Institutes of Health, National Institute on Drug Abuse. Opioid Overdose Crisis. https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis
[2] Florence CS, Zhou C, Luo F, Xu L. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. *Med Care*. 2016;54(10):901-906. doi:10.1097/MLR.0000000000000625.
[3] U.S. Drug Enforcement Administration. 360 Strategy – Diversion Control. https://admin.dea.gov/360-strategy-diversion-control
[4] CDC Newsroom. CDC Advises Against Misapplication of the Guideline for Prescribing Opioids for Chronic Pain. https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html
[5] National Academies of Sciences, Engineering, and Medicine. 2017. Pain management and the opioid epidemic: Balancing societal and individual benefits and risks of prescription opioid use. Washington, DC: The National Academies Press. doi: https://doi.org/10.17226/24781.

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being cut off from prescriptions (forced tapered or abandoned) due to physician misinterpretation of the CDC guidelines. Unfortunately, these reports share that some of these patients have thereby turned to illegal opioids. For many Americans who suffer from chronic pain, these misapplications lead to them not receiving pain treatments that might otherwise be a part of a healthy pain management regimen that result in measurable improvements to life functions, including a return to work, quality of life, and improvement in activities of daily living. Providing the medical community with proper education and training is essential to providing adequate care to patients who suffer from acute and chronic pain.

On May 9, 2019, the U.S. Department of Health and Human Services (HHS), in conjunction with the U.S. Department of Defense (DOD), the U.S. Department of Veterans Affairs (VA), and the Office of National Drug Control Policy (ONDCP), released its Comprehensive Addiction and Recovery Act of 2016 (CARA) legislated final report, *Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations.*[6] This report, made by 29 members with backgrounds in pain, addiction, mental health, state medical boards, primary care physicians, nurses, pharmacists, veterans, and professional medical organizations, was released for key stakeholders to assist the public at large, private stakeholders and government agencies in their attempts to improve the quality of pain care given to patients in the context of the current opioid crisis, as well as aiding in the proper interpretation of CDC guidelines.

Among other things including education, risk assessment, non-opioid treatments, the Best Practices Final Report emphasizes a key distinction between patients – there is the patient with chronic pain, on stable doses of opioids, in which the dose does not escalate (and does not have any indications of opioid misuse, has met the requirements of their treatment agreement, and are generally compliant patients with clear benefits of opioid treatment) while the patient remains under a physician's care.

This is in contrast to another group of patients (with opioid use disorder, at risk for overdose and death) who exhibit drug seeking behavior such as escalating doses, doctor shopping, purchasing illegal drugs, and resorting to criminal activity to support their lifestyle who would clearly require a different approach to treatment than the previously mentioned group.

Anecdotally, patients whom I know to have been on long term stable doses of pain medicine are complaining of no longer being able to obtain proper pain treatment and their doctors pointing to pressure from the DEA and/or citing the CDC guidelines. I have included an example of such a patient letter as an attachment to this letter. I am concerned about the unintended consequences of clinically appropriate patients no longer receiving or having access to the appropriate treatment due to ongoing misunderstandings between the physician and regulatory agencies such as the DEA.

To this end, I would appreciate your response to the following questions:

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[6] U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Retrieved from U. S. Department of Health and Human Services website: https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html

1. What instructions does the DEA give to pharmacists and physicians as they treat chronic pain patients?
2. Do these instructions differentiate between the two types of patients described above? Those on stable, chronic doses and those exhibiting drug seeking behavior?
3. If a patient has been on a chronic, stable dose of opioids, is there any reason that a doctor would feel pressured by the DEA to alter their practice of medicine by changing or force tapering the patients from opioid medications?
4. How has the DEA incorporated the recommendations laid out in the HHS Pain Management Best Practices Inter-Agency Task Force Report in its interactions with pharmacists, physicians, and other CDP registrants?
5. What other instructions or guidelines does DEA use in its efforts to properly educate and train pharmacists, physicians, and other CDP registrants?
6. What, if any, empirical trends have you seen from any production quota adjustments made by the DEA in its effort to reduce the amount of drugs available for illicit diversion and abuse while ensuring that patients will continue to have access to proper medicine in the medically supervised arena?

Tools like the *Pain Management Best Practices Inter-Agency Task Force Report* should be seen as a resource to better equip the DEA and other key stakeholders while seeking to combat the opioid crisis. Empowering the registrant community with instruction in best practices will serve those in need of medication who are combating pain in the acute and chronic period. This should prove to be a help as we all seek improvement of the patient's well-being and overall improved function. I look forward to your response.

Sincerely,

Bill Cassidy, M.D.

Bill Cassidy, M.D.
United States Senate