February 5, 2025

VIA ELECTRONIC TRANSMISSION

The Honorable Earl L. "Buddy" Carter
Chair
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Diana DeGette
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Carter and Ranking Member DeGette:

On behalf of the undersigned organizations, we appreciate your leadership in addressing the fentanyl epidemic, a crisis that has devastated families across the country, and for convening the hearing entitled, *Combatting Existing and Emerging Illicit Drug Threats*, scheduled for Thursday, February 6, 2025.[1] As physicians, we write to provide a clinical perspective on this issue, particularly regarding our compliance with the Controlled Substances Act (CSA) and the critical distinction between fentanyl approved by the U.S. Food and Drug Administration (FDA) and illicit fentanyl analogues.[2]

We care for patients who experience severe, chronic intractable pain due to conditions such as advanced cancer, complex surgical interventions, and neurological disorders who require carefully prescribed individualized pain management strategies. This often involves the use of regulated medical devices and controlled substances under the CSA. For example, patients with cancer pain caused by tumors that have spread to the skeleton or that are compressing nerves, or individuals suffering from severe spasticity disorders (i.e., cerebral palsy, multiple sclerosis, stroke, brain/spinal cord injury), may require an intrathecal drug delivery system.[3] Sometimes colloquially termed "pain pumps," these implantable devices deliver medication directly into the spinal fluid, providing effective pain relief while minimizing systemic opioid exposure. These therapies allow patients to have significant improvement in symptoms and quality of life as compared to oral medications. Some of the FDA-approved pain medications used in these devices—such as morphine—are classified as Schedule II drugs due to their high potential for abuse. Yet, they are essential for certain chronic disabling medical conditions and safe when prescribed and carefully monitored by a physician.

As you know, the U.S. Drug Enforcement Administration (DEA) oversees a rigorous regulatory framework for controlled substances to prevent misuse and diversion while ensuring appropriate medical access. Physicians and other clinicians must register with the DEA to prescribe, administer, or dispense controlled substances, including FDA-approved fentanyl and other opioids. This registration must be renewed every three years, and registrants must comply with strict record-keeping, safety reporting, prescription monitoring, and storage requirements. The most restrictive classification is Schedule I. The

[1] House Committee on Energy and Commerce, (2024, January 24), Chairmen Guthrie and Carter announce health subcommittee hearing on illicit drug threats. https://energycommerce.house.gov/posts/chairmen-guthrie-and-carter-announce-health-subcommittee-hearing-on-illicit-drug-threats.
[2] 21 U.S.C. §§ 801-971 (1970).
[3] These are prescribed when oral opioids or other pain management strategies are ineffective or cause intolerable side effects.

CSA defines a Schedule I controlled substance as a drug or other substance that has a high potential for abuse, has no currently accepted medical use in treatment in the U.S., and lacks accepted safety for use under medical supervision.[4]

Illicit fentanyl analogues are far more potent and deadly than prescription opioids. Until federal authorities and Congress stepped in seven years ago to temporarily add them to Schedule I, these substances lived outside of this carefully constructed and regulated ecosystem.[5, 6] As federal agencies continued to report on the status of the fentanyl and opioid crisis annually, Congress extended the temporary scheduling several times, and it is currently set to expire on March 31, 2025.

Given the above, maintaining illicit analogues under a temporary Schedule classification is not a sustainable or rational approach. Continually revisiting its classification creates confusion about the dangers of these substances and hampers efforts to address the crisis comprehensively. Illicit fentanyl analogues have an extraordinarily high potential for abuse, have no accepted medical use, and cannot be used safely under any circumstance—even with medical supervision. In addition, illicit fentanyl analogues have become widely accessible on the streets and through online sources. This accessibility (and affordability) has caused chaos for patients as many pursued illicit fentanyl analogues, looking for pain relief and believing them to be equivalent to fentanyl but not understanding the dangers of these compounds, which do not carry the imprimatur of FDA approval and are not used under the careful monitoring by their physician.[7, 8] Finally, the uncertainty surrounding the continued temporary scheduling undermines the continuity of the DEA's ability to fulfill its core mission of regulating access to controlled substances to prevent misuse, diversion, and illicit distribution of controlled substances. To this end, we commend recent bipartisan efforts in the Senate to advance legislation addressing the fentanyl crisis by appropriately categorizing fentanyl analogues under the CSA, while preserving access to scientific research on pain management and medication-assisted treatment.[9] We believe these efforts build on the momentum from last Congress, where similar legislation passed the House with bipartisan support.[10]

As you consider permanent scheduling and other changes to the CSA, we urge you to protect the role of FDA-approved fentanyl and other opioids in clinical medicine. Specifically, we request that you make a technical correction in the SUPPORT for Patients and Communities Act to maintain the long-standing practice of the DEA registrants obtaining opioid and other compounded intrathecal medications to fill patients' pain pumps. These pumps require periodic refilling of the medication reservoir to maintain therapy. The medications are often prepared by outside pharmacies pursuant to a physician's prescription. For many years, these syringes of sterile medications would be delivered to the physician's office, where the refill would be completed. For those patients who are too disabled to make the journey to the physician's office, some of the compounding pharmacies employ nurses who are trained in these refill techniques and would take the medications to the patient's home and perform the refill there.

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[4] 21 U.S.C. § 812(b)(1) (1970).
[5] Drug Enforcement Administration (2018), Schedules of controlled substances: Temporary placement of fentanyl-related substances in schedule I, Federal Register, 83(25), 5188-5192.
[6] SUPPORT for Patients and Communities Act, Pub. L. No. 115-271, 132 Stat. 3894 (2018).
[7] Cicero, T. J., Ellis, M. S., & Kasper, Z. A. (2020). The transition to illicit drug use following prescription opioid exposure: A review of empirical evidence and future directions, *Preventive Medicine*, 128, 105852. https://doi.org/10.1016/j.ypmed.2019.105852.
[8] National Institutes of Health. (2022), The opioid crisis and the black market: How supply and demand shape illicit opioid use. *National Library of Medicine*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9306091/.
[9] Senate Judiciary Committee (2025, January 30), Grassley, Cassidy, and Heinrich propose a permanent scheduling fix for fentanyl-related substances. United States Senate, https://www.judiciary.senate.gov/press/rep/releases/grassley-cassidy-heinrich-propose-permanent-scheduling-fix-for-fentanyl-related-substances.
[10] Clerk of the U.S. House of Representatives, (2023, May 25), Roll Call 237: HALT Fentanyl Act. Office of the Clerk, U.S. House of Representatives, https://clerk.house.gov/Votes/2023237.

Unfortunately, a misinterpretation of the SUPPORT Act threatens this critical treatment option by preventing pharmacies, including compounding pharmacies, from dispensing controlled substances for use in pain pumps.[11] Federal law restricts pharmacies from dispensing controlled medications to anyone except the end user. An exception to this prohibition was created by the SUPPORT Act to allow direct dispensing to the practitioner, but only for medications used to treat opioid use disorder.[12] This restriction has created significant logistical barriers, forcing patients and providers to navigate burdensome workarounds such as requiring homebound patients to execute a power of attorney agreement or personally receive and store highly concentrated, perishable opioids—both of which pose risks to patient safety and medication security.

The DEA and the U.S. Department of Justice both recognize this issue but have stated in conversations with physicians and compounding pharmacies that the only solution is a legislative fix. Moreover, the DEA has in the past stated that they would at least consider issuing temporary guidance stating that they do not believe the wording prohibits dispensing controlled substances used in intrathecal pain therapy to physicians. However, this document has yet to be released, thereby sowing confusion for practitioners serving this vulnerable population.

Because this issue cannot be resolved administratively, a legislative fix is necessary to restore access to intrathecal pain pumps without unnecessary regulatory burdens. This targeted correction would protect patient access to evidence-based pain management, maintain proper DEA oversight of controlled substances, and prevent undue administrative challenges for both physicians and patients. Ideally, this fix would include changes to the code allowing the dispensing of these medication syringes to the prescribing physician or their designate (such as the refilling agency). Moreover, we recommend amending the referenced statute to add Schedule II medications to the list of approved schedules for these deliveries.[13]

We appreciate your leadership in addressing this crisis and urge Congress to enact policies that effectively combat the illicit fentanyl epidemic while preserving access to legitimate, physician-directed pain management. We look forward to collaborating with you on statutory measures that balance public health and law enforcement priorities, improve patient care, and promote responsible prescribing practices in the fight against fentanyl-related deaths.

Sincerely,

American Academy of Pain Medicine
American Academy of Physical Medicine & Rehabilitation
American Association of Neurological Surgeons
American Academy of Orthopaedic Surgeons
American Society of Anesthesiologists
American Society of Regional Anesthesia and Pain Medicine
American Society of Spine Radiology
Congress of Neurological Surgeons
International Pain and Spine Intervention Society
North American Neuromodulation Society
North American Spine Society

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[11] SUPPORT for Patients and Communities Act, Pub. L. No. 115-271, § 3204, 132 Stat. 3894 (2018).
[12] 21 USC 829a. *See also* Wagner, M. N., & Rosebush, L. H., (October 10, 2024), Make no mistake, pharmacies can still deliver controlled substances to patients, Baker Hostetler, https://www.bakerlaw.com/insights/make-no-mistake-pharmacies-can-still-deliver-controlled-substances-to-patients/.
[13] 21 USC 829a(2).