Hello. I am Dr. Juan Hincapie-Castillo, and I am an assistant professor of Epidemiology. My research is at the intersection of legal epidemiology, pharmacoepidemiology, and injury prevention. I leverage real-world data to evaluate and promote evidence-based policymaking, and my primary focus is on improving prescribing policies and the provision of equitable pain management and safe psychotropic medication use.

I am here today speaking on behalf of the National Pain Advocacy Center (NPAC), where I currently serve as President of the Board of Directors. NPAC is a nonprofit organization that takes no industry funding and advocates for the health and human rights of people living with pain.

This means that I am here today representing the 50 million Americans who live with chronic pain, the 17-20 million Americans with persistent pain so severe that it regularly prevents them from participating in life activities and work, and millions more with acute or episodic pain.

Chronic pain is the chief cause of long-term disability in the U.S., and pain frequently accompanies other disabling conditions.

The explosion of telemedicine amid shutdowns related to the COVID-19 pandemic and related public health emergency [PHE] proved transformative for countless patients with pain and disability who were otherwise unable to access care. For these vulnerable patients, telemedicine extended a needed bridge to critical care – one that the DEA must not now rescind.

Prescribing of Schedule II Substances for Pain

NPAC is chiefly concerned with continuity of care for patients with long-term pain who currently take opioids.

Today, these patients face substantial barriers to care that pose an imminent risk to their health and lives. As public health agencies from the CDC to the FDA have acknowledged, many such barriers stem from government actions like those the DEA considers today.

Two studies by Lagisetty, et. al., published in *JAMA Netw. Open* (2019) and *Pain* (2021), for example, found that upwards of 40% of primary care doctors will refuse to treat a new patient who uses opioids to manage pain. An NBC news piece recently highlighted the plight of a patient who called 150 different providers desperately trying to arrange care.

Disruptions in care are deadly. Many studies show that opioid disruption places patients at increased risks – including a **three to five-fold increased risk of overdose and suicide**. Studies by Glanz et al. in *JAMA Netw. Open* (2019), James et al. in J Gen Intern Med (2019) Oliva et al. in *BMJ* (2020), Agnoli et al in *JAMA* (2021), Fenton et al in JAMA Netw Open (2022), and

Larochelle et al in Jama Netw Open (2022) all found a heightened risk for death, overdose and/or suicide with opioid disruption.

Even destabilization of dosage carries risks that continue for up to two years after dose is destabilized. (Fenton et al. in JAMA Netw Open (2022).

Opioid disruptions are associated with other risks as well, including increased need for emergency medical care and hospitalization. (Mark et al, J Subst. Abuse Treat 2019; Magnan et al JAMA Netw Open 2023).

This life-threatening and health-destabilizing problem affects a substantial number of people: as many as 8 million Americans use opioids to manage pain long-term, more than 3 times the number with a diagnosed use disorder.

The DEA has seen the effects of patient abandonment and opioid disruption firsthand. When the DEA suspended a doctor's license in California, for example, three people died. Another, a wheelchair user with dystonia, was able to stave off withdrawal by using a methadone clinic, but the medication did not manage her medical condition. She suffered persistent spasticity that continuously knocked her out of her wheelchair for several months until she was able to arrange alternative care which required her to travel in that condition to another state.

The threat to life is not limited to overdose or suicide. Kenny Maestas, a quadriplegic living in Colorado who recently testified in the Colorado Legislature, had a heart attack and woke up on a ventilator after an opioid disruption.

At a moment when the street supply is especially dangerous, when the CDC is warning especially about deaths from counterfeit pills, and when overdose deaths continue to escalate, surpassing 107,000 in 2021, making policy decisions to roll back a proven avenue for care and one that put people in harm's way is reckless.

In order to protect continuity of care for this population, our suggestion in alignment with the questions asked in the DEA's framework is as follows:

The DEA should allow telemedicine prescribing for continuity of care in these patients by permitting an established opioid dose from a previous in-person prescriber to be continued using telemedicine.

This approach is analogous to "guest dosing" permitted by SAMSHA in an opioid treatment program (OTP) and is similarly protective of treatment continuity. This is the preferred action and would leave in place existing avenues for care for this population.

Alternatively, the DEA could allow 60- to 90-day initiation via telehealth by a new provider with appropriate documentation that accords with relevant state medical board rules and procedures.

The DEA should also consider allowing a 60-day initiation via telehealth even for new prescriptions via telemedicine for pain in situations where people cannot otherwise physically access care. Often, a physical examination will precede schedule II prescribing for a new opioid prescription, but care deserts in the U.S. are vast, and in-person care is a poor proxy for *bona fide* healthcare relationships.

According to the Health Resources & Services Administration, nearly 100 million Americans live in areas with a shortage of health professionals. Rural areas where many clinics and hospitals have shuttered are especially burdened.

A 2020 systemic review of barriers to access to pain care for older adults in rural areas by Suntai et al (*Am Jol Pall Care*), for example, identified transportation-related issues as a major access barrier to pain and palliative care – precisely the type of barrier mitigated by telemedicine.

All impediments to care and continuity of care are likely to be borne disproportionately by people with disabilities, racialized populations, and people living in rural areas or other healthcare deserts. Disparities in pain experience, biases in pain assessment, and inequities in prescribing for pain based on race, gender, gender identity, and disability are well documented.

In Regard to Prescribing for Schedules III-V

The time-frames proposed by the DEA for schedule III-V medications are out of sync with the realities of the U.S. healthcare system. According to a large survey of wait times for doctor's appointments in the 15 largest metropolitan areas, the average wait time to arrange primary care was 26 days with some cities reporting 45 days. For rural areas or specialist care, wait times are longer.

The DEA should extend telemedicine prescribing all scheduled substances in areas where patients lack realistic access to in-person providers. Doing so would likely require DEA to abandon existing geographic limitations which reflect an anachronistic, pre-telemedicine world.

These considerations are extremely important considering the continued increase in drug-related overdoses in the country. Patients living with opioid use disorder also need to have access to life-saving medications that can be prescribed by telemedicine.

The Government's Interest in Protecting Against Diversion & Evidence of Success of Telemedicine Prescribing amid COVID-19

Importantly, the flexibilities that allowed for telehealth prescribing during the PHE do not appear to have resulted in documented harm: a rise in prescription-related drug overdose deaths is not evident in provisional death data from the National Center for Health Statistics.

On the contrary, studies that have examined the impact of telehealth prescribing during the PHE found, not surprisingly, that telemedicine prescribing reduced overdose mortality. Notably, three major studies focused on buprenorphine prescribing via telemedicine prescribing show – including a major study in which the lead author was Christopher M. Jones, the former Director of the National Center for Injury Prevention and Control at the CDC and the current Director of the Center for Substance Abuse Prevention at SAMSHA, show that telehealth prescribing reduced overdoses, providing a literal lifeline to patients who experience lapses in and barriers to care.

Proper Guardrails

With regard to the additional question DEA asked in its framework about appropriate guardrails should the agency extend tele-prescribing of controlled medication, the best solution is for PDMPs to be modified to include the mode by which the prescription is dispensed to identify telemedicine prescriptions. Nevertheless, any such modification should be accompanied by an explicit avowal from the DEA that telemedicine prescriptions are not inherently inferior nor suspect to avoid their being denied by pharmacy chains (something we saw during the pandemic by major chains in buprenorphine prescribing). A separate recordkeeping system for providers is not a good idea; it raises cost, burden, and security concerns and a duplicative system increases risks of error that may endanger patient safety.

Thank you for your time and consideration.