



The Convergence of Public Health and Individual Rights



www.ciaag.net



774-262-6671



info@ciaag.net

June 26, 2023

Health & Human Services
Secretary Xavier Becerra
200 Independence Avenue, S.W.
Washington DC, State, 20201

Re: National Pharmacological Supply Chain

Dear Secretary Xavier Becerra,

I am the Vice President of CIAAG; a national non-profit organization dedicated to the convergence of public-health policy and individual rights. As an organization, we prioritize patient safety and wellbeing in policy discussions, along with addressing any potential unintended outcomes resulting from changes within the healthcare system and access to care.

I am writing to your office today regarding patient access to opioid analgesics for the treatment of pain and illness. The United States has embarked upon a series of national strategies to change the way healthcare is provided with a focus on prevention by utilizing opioid sparing policies. In response to this work, the Drug Enforcement Agency has taken action, reducing the manufacturing quota for the nation's medicinal supply of opioid analgesics. There has been a [40+% reduction](#) (1) seen between the years 2012 - 2020 alone, with additional cuts each subsequent year.

In addition, the manufacturers and distributors of opioid analgesics have been a party to a number of lawsuits emanating from state governments, asserting the pharmaceutical industry's liability for the nation's "opioid crisis." The outcomes of these lawsuits have varied, some rulings were overturned and/or dismissed as seen in [Oklahoma ex rel. Attorney General of Oklahoma v. Johnson & Johnson](#) (2) where the lower court was found to have wrongfully interpreted the state's public nuisance laws, leading to a dismissal of the case. Other lawsuits concluded by finding the manufacturer of these products legally liable for their role in "contributing to the nation's opioid crisis".

On July 21, 2021, a \$26 billion offer to settle was made by opioid manufacturer Janssen Pharmaceuticals (parent company of Johnson & Johnson) and the “big three” distributors, McKesson, AmerisourceBergen, and Cardinal Health (“the Distributors”) to resolve their [liabilities](#) (3) in over 3,000 opioid crisis-related lawsuits nationwide.

One of the stipulations of the aforementioned lawsuit was for Cardinal Health to take steps in addressing the safety of controlled substances. In response, Cardinal Health implemented a [Controlled Substance Monitoring Program](#) (4), to prevent the diversion of scheduled medications. As a part of this change (and without explanation), Cardinal Health suspended select pharmacies' ability to order controlled substances. The criteria/parameters used to select pharmacies for suspension are unknown. This abrupt change in the distribution channels created by Cardinal Health caused an immediate disruption in the supply chain, negatively impacting California residents; an outcome that could have easily been foreseen and prepared for. Despite having advanced knowledge of this upcoming change (and its potential to negatively impact patient care), there was no safety plan in place to ensure displaced patients would be able to transition care to a different pharmacy without incident.

For the past 10+ years, I have required the use of opioid medications to manage the pain I experience from dermatomyositis; a rare, incurable, autoimmune disease. During this time, I have used the same small, local community pharmacy without incident until a few weeks ago.

Upon arriving at my pharmacy to pick up my monthly medications, I was provided a short-term prescription containing 10 days worth of medication (rather than the usual 30-day prescription, as written by my provider). The pharmacist advised, they would no longer be able to fill my prescription for controlled medication and I would need to find a new pharmacy to participate in my care. The pharmacist provided me with a note indicating the reason for this change; it stated this change was due to “Cardinal Health suspending Tuttle’s Pharmacy from ordering all controlled substances.”

I notified my physician as he had to write a new prescription in order for me to transfer my care to another pharmacy. I asked that he send it to CVS Health to be filled. I selected CVS Health as they are the preferred provider in my health insurer’s network (Aetna). My provider issued a new prescription and it was sent to CVS Health on May 22, 2023.

On Friday June 2, 2023, I spoke with the pharmacist at CVS to ensure my prescription would be ready for pickup the following day (the date the prescription was written to be filled). The pharmacist proceed to advise that:

1. My prescription was “rejected” and
2. They would not accept me as a patient

I was told that my rejection was as a result of the pharmacy not having enough stock, that their store location was “near its limit of patients they were allowed to serve” and as a result, CVS was unable to accept me as a patient.

CVS Health received the initial prescription request on May 22, 2023. During the time between May 22nd and June 2nd, CVS made no attempt to contact or inform me of their decision to refuse me as a patient along with the denial of my prescription. The pharmacy’s failure to serve me caused a continuity of care disruption as I was now without my necessary medication. The act of holding onto a controlled substance prescription and not advising the patient that they will be refused service until the due date of the prescription refill is irresponsible and equates to gross misconduct on behalf of CVS Health’s employees. CVS Health had the professional responsibility to notify me immediately that they would not be accepting my prescription request or assuming my care; permitting the adequate time I needed to find an alternative pharmacy in an effort to protect my continuity of care, health and wellbeing.

Pharmacies have long been declared “stewards” with a responsibility to ensure patient safety in regards to controlled medications. A part of this responsibility includes ensuring patients who use scheduled medications do not experience continuity of care disruptions via denial of access to their legitimate prescriptions.

Cardinal Health was aware of their decision to suspend Tuttle’s Pharmacy's controlled medication ordering ability. This disruption resulted in approximately 1,500+ patients to be displaced and in immediate need of a new pharmacy to assume their care. Despite this advanced knowledge, Cardinal Health did not take the necessary steps to ensure other pharmacies in the area had the capacity to take over these newly displaced patients in need of care.

To my knowledge, my medical history/EMR was not reviewed prior to the pharmacist at CVS making this decision. My physician was not asked for documentation to show justification for the dose of the medication that I take. There was no review of my care plan (which would have shown that I am actively tapering my dose consistent with [HHS guidance/recommendations](#) (5) published in 2019 titled “HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics.”) It appears this was a unilateral decision made by a pharmacist based on unknown criteria.

In April 2019, both the [CDC](#) (6) and [FDA](#) (7) issued announcements warning against the practice

of abrupt or rapid discontinuation of opioid medications due to the concerns of patient suicides, psychological harms, continuity of care interruptions, destabilization and the risk of [adverse consequences](#) (8), including opioid-related hospitalizations and emergency department visits.

Despite these clear statements from two federal agencies, the pharmacist at CVS Health did nothing to ensure my continuity of care was not disrupted. Instead of alerting me upon receipt of the prescription that they were not going to accept me as a patient, the pharmacist waited until approximately 4:30pm on a Friday afternoon to advise me they would not help me and I would need to find another pharmacy, which is a clear impossibility at that time of day on a Friday afternoon. This left me to face a weekend without my prescriptions, effectively putting my health and well-being at risk due to a potential abrupt and rapid discontinuation of my medication. The FDA has made it clear that this practice of rapid discontinuation is an extremely risky endeavor as abruptly discontinuing opioids in an opioid dependent patient can be dangerous. As a “steward of the opioid crisis”, the pharmacist at CVS Health had a duty to ensure that my continuity of care was not disrupted as I could potentially face these risks. If CVS Health was unable to provide the requested services (filling my prescription/assuming my care), they had a duty to advise me as soon as they were aware.

I sought additional pharmacies to take over my prescription needs and have been denied by 3 different stores. All locations are claiming they are at their “legal limits of patients who are prescribed opioids analgesics that they are allowed to serve” and therefore, are unable to assume my care.

The continuity of my medical care has been disrupted and my health put at risk due to a lack of planning by the individuals in charge of this action. This was an easily foreseeable event that should have been planned for and managed. There was no planning to ensure the safety and well-being of the patients who were displaced by this action.

We need a system put in place for patients dependent on opioids who are facing sudden disruptions in their care as a result of health policy changes or supply chain issues that impact their ability to access controlled medications. State policymakers should have been able to foresee that the reduction in the supply chain due to the recent lawsuit settlements would impact patients’ ability to access their necessary medications. Further, the individuals involved in the planning of these actions should have taken steps to ensure a backstop was put in place to protect the continuity of care for the affected/displaced patients.

There must be flexibility in the number of patients providers and pharmacies are able to serve when supply chains are disrupted as a result of public-health policy changes; this includes alterations in

the manufacturing and/or distribution quotas of controlled medications. The legal agreements of a pharmaceutical company should not impede patient access. Our state and federal lawmakers have a duty to ensure the safe delivery of medical care to all citizens; it is not ok to engage in acts that result in the abandonment of a particular group of individuals based solely on their medical needs and the types of medications they require.

The actions of Cardinal Health have resulted in patients being displaced with no plan or assistance to navigate their sudden disruption in accessing necessary medications. It is important to note, many of these patients are extremely sick and often unable to advocate for themselves especially when faced with these types of situations.

This is not a new issue. Lawmakers have been alerted by citizens across the nation for over 5 years that the opioid-sparing policies are negatively impacting the public's health and well-being; yet, there has been no tangible actions or changes in the national campaigns to address these issues. The current structure of national opioid policies have created a dangerous environment for individuals in need of medication management for their illnesses/conditions. Individuals who need this medication are facing targeted discrimination, inequities, medication insecurity and patient abandonment as a result of new public-health policies. It is entirely inadequate and unacceptable for individuals dependent on scheduled medications to be left without the ability to continue their current care plan due to poorly executed public health policies. Opioid dependent patients like myself are left with little to no warning about changes in our care (including access to valid prescriptions) which places us at an extreme disadvantage. These types of practices lead to outcomes that go directly against Cardinal Health's original [stated goals](#) (9) of "working around the clock so that life-saving medicine gets to those who need it – safely, securely, and on time".

It is irresponsible for entities like Cardinal Health to continue with its current business practice of arbitrarily changing the rules surrounding their manufacturing and distribution of scheduled medications. In doing so, they have interfered with the care of countless citizens across the nation. By continuing this practice, Cardinal Health is tying the hands of the pharmacists that serve the patients in our community and they are harming small businesses by refusing to provide them with the same medications afforded to large chain pharmacies. This not only puts patients at risk, it interferes with the free market and is leading to less competition resulting in the creation of pseudo-monopolies.

This has created a major inequity in the pharmacy care system; patients labeled as "opioid users" are actively discriminated against and denied services based solely on their medication needs. The refusal to permit good-faith business practices of small pharmacies (via the actions of entities like Cardinal Health arbitrarily refusing to provide them equal access to medications for distribution)

is creating a clear market advantage for their partners such as CVS Health and their Pharmacy Benefit Managers. CVS Health and other large conglomerates stand to benefit financially when these smaller pharmacies are unable to serve their local community. These unfair business practices are resulting in direct patient abandonment and are putting the health and wellbeing of the citizenry at direct risk.

The actions of CVS Health and Cardinal Health are directly responsible for the disruption of my care (and the care of countless others). We would like to request the creation of a federal committee to review the supply chain issues related to opioid analgesic medications and the development of policy recommendations to address any gaps or inconsistencies.

The CIAAG Executive Team is available to meet to discuss policy recommendations and actions that could be undertaken to address the systemic issues taking place regarding the management and care for those who need opioid analgesics to manage their illnesses/conditions.

Thank you,

Lauren Deluca & Shasta Rayne Harner
Executive Director & Vice President

CITATIONS

1. U.S. Opioid Dispensing Rate Maps | Drug Overdose | CDC Injury Center. (n.d.). CDC. Retrieved June 26, 2023, from <https://www.cdc.gov/drugoverdose/rxrate-maps/index.html>
2. Oklahoma ex rel. Attorney General of Oklahoma v. Johnson & Johnson. (n.d.). Justia Law. <https://law.justia.com/cases/oklahoma/supreme-court/2021/118474.html>
3. DHCS California's Opioid Settlements. (n.d.). DHCS. Retrieved June 26, 2023, from <https://www.dhcs.ca.gov/provgovpart/Pages/California-Opioid-Settlements.aspx>
4. Combating Opioid Misuse. (n.d.). <https://www.cardinalhealth.com/en/about-us/environmental-social-governance/combating-opioid-misuse.html>
5. HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics. (2019, October). CMS. Retrieved June 26, 2023, from <https://www.cms.gov/About-CMS/Story-Page/CDCs-Tapering-Guidance.pdf>
6. CDC Newsroom. (2016, January 1). CDC. <https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html>
7. Research, C. F. D. E. A. (2019). FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering. U.S. Food And Drug Administration. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes>
8. Dowell, D., Compton, W. M., & Giroir, B. P. (2019). Patient-Centered Reduction or Discontinuation of Long-term Opioid Analgesics. *JAMA*, 322(19), 1855. <https://doi.org/10.1001/jama.2019.16409>
9. Understanding the epidemic. (n.d.). <https://www.cardinalhealth.com/en/about-us/environmental-social-governance/combating-opioid-misuse/understanding-the-epidemic.html>