DEAR ADVOCATE ARMY

Do you remember back in April 2019 when the FDA finally broke their silence on the forced tapering of patients off their pain medications across the nation?

Do you know how that announcement came to be?

Storytime:

In 2019, our team made a research discovery that changed the very landscape of advocating for access to opioid analgesic medications for the treatment of pain and illness.

While reading through numerous federal guidance documents, we were able to ascertain the root cause for the push to reduce access to opioid based pain medications in the nation. It was not due to the CDC Opioid Prescribing Guidelines, as so many people were led to believe.

In fact, the real reason was more simplistic. The US Government had embarked upon a unique research project in an effort to reduce healthcare costs to society. This research agenda permitted the issuance of the CDC Opioid Prescribing Guidelines without the necessary clinical research to establish the safety and efficacy of the recommendations within.

While the public was distracted with the issuance of the CDC Opioid Prescribing Guidelines, NIH issued another guidance document that would serve as a complementary strategy; the National Pain Strategy.

The National Pain Strategy sought to change the public's perception of pain and how it should be treated with a focus on self-management. Under the National Pain Strategy, research would be conducted on the live patient community through the use of the electronic medical record (EMR). Instead of patients receiving the current stand of care, they would now be directed to use alternative and/or complementary therapies instead.

Patient outcomes would be documented by the doctor directly into the EMR. Subsequently, clinical researchers would then access the patient EMR's in order to decipher which treatments were shown to be effective and conversely, which ones were not.

The problem with this research?

This research is conducted in the "real-world" setting on private citizens without their knowledge or informed consent. Many providers are also unaware that the now "preferred" alternative/complementary therapies and modalities deemed "best practices" are actually experimental and are being studied on the back end via live-time documentation in the EMR's.

We were shocked upon making this discovery and quickly wrote up our Dossier: Violation of A Nation; outlining our findings. CIAAG founder, Lauren Deluca and CIAAG Vice President, Shasta Rayne Harner, took our report to Washington, DC to share and discuss the implications of our findings and the subsequent effects this research was having on the private citizenry.

Over the course of three days, we met with 9 Congressional and Senatorial offices. We typically met with a staffer; therefore, one could imagine our surprise when we were informed that one of the staffers we were scheduled to meet with was unavailable. We were told that we would instead be meeting with the congressperson.

Our hearts raced upon hearing this information. A federal lawmaker was coming to see us personally! This was unusual.

We stood there, not knowing what to expect. After a few minutes, the lawmaker entered the room with a copy of our Dossier, Violation of A Nation in hand. Clearly, they were aware of our report and its findings.

Upon entering the room, they advised us that they only had 5 minutes as they were attending a congressional hearing and needed to get back to it asap. They turned on the TV that was behind us so they could continue watching the live hearing, in order to not miss a thing, while keeping their meeting with us.

Surprised (but very hopeful) by this turn of events, we were pleased to see our report garnered the personal attention of such a high-powered lawmaker. After some brief introductions and an overview of our findings, the lawmaker asked me, "What do you want from us?"

Without skipping a beat, I advised them that we wanted a formal announcement against the practice of forcibly removing patients off opioid based medications. They had sufficient evidence (at this point) of the substantial harms this practice causes. I vividly remember the following moment when I paused, looked into their eyes, and passionately stated, "It would be irresponsible at this juncture not to."

I truly believe these were the words that made them act. Shasta agrees.

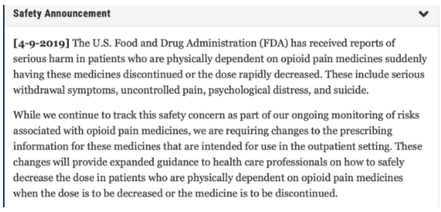
They thanked us for our time and we left the office together. The lawmaker briskly walked down the hall to rejoin their meeting, flipping through the pages of our Dossier; leaving us trailing behind. We were ready to finish our visit at the Capitol.

The next day, we awoke in our hotel to find out; the FDA made a formal announcement advising against the practice of forced tapering.

We did it! The lawmakers listened!

They heard our pleas for intervention and answered them. We couldn't believe it. We were overwhelmed with joy that we, two women who live all the way across the country from each other, who just met 6 months prior, were able to do something so powerful for the pain patient community.

Within weeks of the FDA Announcement, the CDC followed up with an announcement of their own. HHS later followed up with a subsequent announcement as well.



Safety Announcement

[4-9-2019] The U.S. Food and Drug Administration (FDA) has received reports of serious harm in patients who are physically dependent on opioid pain medicines suddenly having these medicines discontinued or the dose rapidly decreased. These include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide.

While we continue to track this safety concern as part of our ongoing monitoring of risks associated with opioid pain medicines, we are requiring changes to the prescribing information for these medicines that are intended for use in the outpatient setting. These changes will provide expanded guidance to health care professionals on how to safely decrease the dose in patients who are physically dependent on opioid pain medicines when the dose is to be decreased or the medicine is to be discontinued.

Content current as of:
04/09/2019

Regulated Product(s)
Drugs

Topic(s)
Safety - Issues, Errors, and Problems

Patients in pain still have a long way to go before their rights are properly restored and their healthcare is no longer subjected to the improper influence of third parties. Nevertheless, we were able to get these federal agencies to acknowledge the dangers patients face when subjected to the forced removal of scheduled medications. The events of that day, a result of our Dossier, greatly reduced the rate at which this practice was taking place.

There is still much work to be done. In order to ensure the health, safety and liberties of all citizens, we must advocate for the implementation of regulatory oversight, transparency, and the restoration of informed consent in human clinical trials.

This is one small example of how hard work, dedication, and a refusal to accept "no" for an answer, resulted in a massive change that helped millions of people across the nation and even, across the globe.

Remember, Together We Are #CIAAGStrong!!!

Thank you,

Lauren L. Deluca, CPCU, API, AINS

Founding President & Executive Director

Chronic Illness Advocacy & Awareness Group dba CIAAG