To: Chronic Pain Patients of Kaiser Permanente Northern California Region – and others interested in the current chaos surrounding our prescribed pain and anti-anxiety medications (June 28, 2023)

Introduction to This Presentation

The purpose of this presentation is to provide an analysis of the recent mandatory tapers and "shortages" of both prescription pain and anti-anxiety medications at Kaiser Permanente, Northern California Region. It is meant to help patients and their families understand the drastic changes in pain management that have occurred since the Fall of 2022. In order to confront this problem, it is imperative that all Kaiser chronic pain patients have the same knowledge of the most current causative factors.

A Brief Introduction of Myself and My Investigation:

I am a retired RN with over 40 years of healthcare experience. The principal focus of my career focused on healthcare regulations, risk management and patient safety. My most recent position was as National Leader for Risk and Patient Safety for Kaiser Permanente. Any statements made in this article are presented to the best of my knowledge but may not be complete or may require further investigation. Anyone having more accurate information is encouraged to contact me so that I can update this document. As a victim of a mandatory taper myself and seeing the suffering of others, I was specifically motivated to understand the reasons behind Kaiser's draconian decisions.

My sources, listed at the end, include written statements from Kaiser Permanente leadership, NCAL Pharmacy Leadership, multiple news and journal articles and my first-hand experiences interacting with staff in my specific NCAL medical center. I also had conversation with the Executive Liaison in the CEO's office. I am most grateful for the support of the California Doctor Patient Forum on Facebook.

Investigation Findings <u>Overview:</u>

After over 7 months of intensive research, I have determined that the following statements best describe what has occurred with the pain management policies of Kaiser NCAL**. I will explain each of these conclusions in detail in this paper.**

- As a direct result of the impending new restrictions that would come with the National Opioid Settlement with the three major distributors, AmerisourceBergen, Cardinal Health, and McKesson of July 2022, Kaiser Permanente NCAL made an agreement with their opioid /controlled substances distributor. The agreement was made with the goal of continuing their contract with the distributor as well as reducing the risk for their TPMG physicians. A staff employee, who wishes to remain anonymous, told me that they were given a "gag order" by Med-Legal. The order was that they should not discuss this agreement openly with any patient. Instead, they were given various "rationales" dealing with patient safety and guidelines, none of which were the root cause of their decision. **The essence of the agreement was that a select group of patients; those posing the highest risk of eliciting a "red flag" or "suspicious order" warning by the distributor were to be put on "Mandatory Tapers."** The patients identified were determined by a pharmacy protocol and NOT by the patient's own physician. In fact, the physicians were told that they did not have a choice in the selection of these patients, nor could they intervene to "pause" or stop the taper. No risk/benefit discussion was held with those patients, and they were forced into a reduction of their medications without any feedback in the process whatsoever. The cruelty of this practice should be apparent with no further explanation

needed. By January of 2023, most patients meeting the criteria had been started on their tapers. (1)

- In addition to the patients caught up in the mandatory tapers, other patients still faced **difficulties obtaining their pain and anti-anxiety medications**. **Due to a new restraint being put on the distributors called a "threshold," Kaiser pharmacies were faced with shortages of controlled substances.** A patient with a legitimate prescription could not determine ahead of time if their medication would be filled, and if not filled, how long they might have to wait. For many, this gap in obtaining their pain medications was every bit as difficult as those directly put on a taper. I have direct knowledge of a chronic pain patient in NCAL who waited over a week for their prescription to be filled. This will sound familiar to non-Kaiser patients as the same mechanisms are in play. These will also be described in detail in the following sections. (2)

A DETAILED LOOK AT THE COMMON DENOMINATOR FOR BOTH MANDATORY TAPERS AND SHORTAGE OF CONTROLLED SUBSTANCES at the Kaiser NCAL Region.

The common cause for Kaiser's **sudden changes** was, in fact**, the National Opioid Settlement and its INJUNCTION** finalized in July of 2022. Although prior to this settlement many patients obviously have suffered greatly from misapplied oversight of the DEA, the CDC and the FDA, something additional and more ominous had occurred here. The new requirements distributors faced due to this settlement were neither transparent, nor had any significant (if any) medical input.

In the simplest terms, when 41 of the 50 Attorneys Generals won this National Opioid Settlement, it came with an "Injunction" that ADDED requirements for what controlled substance distributors must do. The Court Ordered Injunction was designed to keep the distributors tightly in line with already existing DEA regulations and CDC Guidelines…but it went further. Whereas before, a "suspicious order" or "red flag" order could be discussed between the physician, the pharmacist and the distributor, the injunction mandated an absolute "HALT" to that order. If the distributor thought the order met one of these criteria, it was stopped cold, and the prescribing physician was immediately also reported to the DEA. Note how critical this change is. No physician autonomy, no patient involvement, no risk/benefit discussion…just STOPPED. To add to the sinister nature of the injunction, the "suspicious orders" and "red flags" are often vague, and as such, get interpreted by the distributor in the strictest sense possible. If for example the CDC GUIDELINE says patients should "ideally" be started at less than 40 MME, the distributors, pharmacists, and physicians are going to take that as a hard limit. If the CDC says use care when prescribing opioids and benzodiazepines together, everyone now uses this as another "hard stop." No clinical judgement is allowed, regardless of how long and how safely a patient was managed on these together. (2)

The second thing the injunction did was require the distributor to establish THRESHOLDS for each type of controlled substances. This is very different than the quotas that the DEA was already setting yearly. Whereas a "QUOTA" is the DEA's limit to what can be manufactured in any given year, a 'THRESHOLD" is a monthly limit on what the distributor can release to each pharmacy. These thresholds are calculated based on an algorithm for each specific pharmacy. (It is not based on what an individual patient is being prescribed) The receiving pharmacy has no say in the threshold levels*** and in fact, by this injunction cannot even be told what their threshold is!!!! So, when a pharmacy tells you they don't know when they are going to be getting medication "x"…they truly don't know! (***there are mechanisms buried deep within the injunction that would allow a pharmacy to request more medication – but none have been willing to do this. Which pharmacy in their right mind wants to go up against this court injunction and the DEA?) (3)

Consequences of the Injunction on Kaiser Patients and likely other Chronic Pain Patients

What happened before July 2022 was horrific for patients and physicians, what happened after July 2022 was unfathomable. For Kaiser patients in NCAL especially, it was SUDDEN, BRUTAL and without reasonable explanation by the patient's physician. Memos from NCAL Pharmacy Leadership talked about concern for patient safety, but not one piece of information mentioned the known risks of mandatory tapers on "legacy" patients; those patients who have been on prescribed opioids for an extended period-of-time AND HAVE BEEN STABLE AND DOING WELL. There was no discussion with the patient on the possibility of increased suicidal ideation, actual suicide, long-term anxiety, or depression; not to mention unmanaged pain. (3) The patient population most effected were either disabled or seniors or both. These population groups have difficulty accessing "alternative pain management" such as acupuncture or yoga, and in some cases are alone and home bound. This protocol came with no attached mental health or pain management referral. If one asked for a mental health referral it, in some cases, took months. Kaiser Leadership, including the CEOs office has been unresponsive and uncaring of pleas for help. Kaiser physicians have been openly hesitant to go against their physician leadership and, also of course, in fear of the DEA. Medicare has turned a blind eye and ruled that these cases are "standard of care met." Until just recently no one has been able to gain support for helping these thousands of chronic pain patients at Kaiser, and the millions more across the nation.

Some Recent Hope in California

There have been three recent causes for hope.

1. The DMHC recently ruled in favor of a patient who had been on a mandatory taper and ruled Kaiser must return them to their previous dosage
2. The Medical Board of California has recently updated its guidelines on the management of chronic pain and is leaning much more in favor of compassionate care.
3. A new Bill, called Krissy's Bill, will be going through the California State Senate in January of next year. If passed, physicians in California could no longer be criminalized for prescribing in good faith and mandatory tapers would be forbidden. In addition, it will address how the money is being utilized from the opioid settlement and help redirect appropriate funds to chronic pain patients as needed. Finally, we will be asking for a refocus of DEA resources to:
    - secure medication distribution and deliveries
    - rollback restrictions on production of needed meds
    - refocus efforts from targeting doctors and clinics to targeting street meds.
    - changing the algorithm so that when doctors retire in an area other doctors can pick up patients without fear of being red flagged

What Can You Do

1. **If you are not already, please join the Facebook group "The California Doctor Patient Forum." Become active in this group. There is much work to be done.**
2. File complaints with either the Department of Managed Healthcare (DMHC) or Medicare (depending on your age and status.) Flood them with complaints (4)
3. Know you are not alone. Together we will win!

Submitted by Patricia A. Irving, RN, MEd, CPHQ
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Addendum 1 – Documents from Kaiser – mandatory taper

In response to my Kaiser grievance asking to be removed from the MANDATORY Taper and to be allowed to work directly with my PCP, I received the following response (Jan 14, 2023) "The Assistant Chief advised that your PCP explained new protocols but in place by the Permanente Medical Group (TPMG**)..These protocols in part are in place and rigid due to pressure pharmaceutical companies not providing meds to pharmacies who are not complying with their guidelines. So it is not just federal regulations that are dictating the decisions made by TPMG."**

In addition, NCAL Pharmacy Operations released the following statement on January 23, 2023. **"Kaiser Permanente prescribers and pharmacists are reviewing opioid treatment plans and prescriptions in response to new pain management recommendations issued by the CDC, and to a legal settlement between wholesale drug distributors and the government."** They also wrote **"Because of nationwide changes in supplies, prescribing, and dispensing controlled substances affecting both KP and non-KP pharmacies, some pharmacies may run out of certain medications."** Anyone familiar with the 'new CDC Guidelines" would know that they came out in 2022 and were just that - guidelines. To suddenly and radically change an entire organization's pain management policy based on these "not so new" guidelines is difficult to believe. The "CDC made us do it" was the cover story they told physicians and staff to use when explaining the new protocol to patients.

Addendum 2 – The Settlement and Injunction

As early as 2017, acting on the incorrect premise that prescription opioids were the primary cause for the opioid crisis, Attorneys General from 41 of the 50 states began a full-on assault to obtain retribution from all entities they believed were responsible for the "Opioid Crisis." This included opioid manufacturers, distributors, and pharmacies. Their news press releases were full of promises to obtain enough money that they could "fix the opioid crisis." How exactly that was to be accomplished was going to be left up to each state. Lawsuits were soon filed against CVS, Walgreens, Walmart and later Johnson and Johnson. They also filed a joint lawsuit against the three main opioid distributers – AmerisourceBergen, Cardinal Health, and McKesson which is the focus on my article.

On July 21, 2021, the National Association of Attorneys General announced that they had won a 26-billion-dollar settlement against these three distributors.. They also won a **court injunction*** that would ensure that distributors and pharmacies made major changes to how they did business. The described intent was to "improve the safety and oversight of the distribution of prescription opioids" but the unintended consequences to these injunctions have been far reaching and have caused incalculable harm to both chronic pain as well as patients with mental health disorders.

*For reference, **an injunction** is a court order requested by a plaintiff if they contend that the harm that the defendant caused cannot be effectively remedied by an award of money. In this case the court agreed with the AGs that the distributors should be required to add substantially increased measures to identity suspicious orders from their customers. The court ordered this injunction be in place for 10 years. The judge also ordered that there be a third-party monitor for the first five years.

A Closer Look into the Injunctions and Why They Add a New Layer of Restrictions:

For reference, the settlements and injunctions are available in full using the following link: https://www.in.gov/attorneygeneral/files/Final-Distributor-Settlement-Agreement-3.25.22-Final.pdf?fbclid=IwAR0b4MZUsMci_tcGy5fSLbLopfXZzUTF66HFwbtAc8qbn-U35CC5J0KY5NU

The injunctions are either listed as "Exhibit P" or "Q" and appear toward the very end of the documents. This is here for reference only. I will give a highlight below.

In even a quick read of the Injunctions you will notice several things. Many of the restrictions have come directly out of existing DEA and CDC "play books." For example, there is language for "Red Flags" and "Suspicious Orders" that have been inserted with almost no change from previous DEA operational norms. You can find a complete list of Red Flags and Suspicious Orders used in the injunctions listed at the end of this presentation. Please read these if this is a new concept to you. A quick example of two red flags is "Cash Prescriptions" and a second is "Out of Area Patients." The DEA and the injunction consider "Suspicious Orders" as among other things, orders of unusual size, those deviating from a normal pattern, and orders of unusual frequency." Purposely vague)

So, if all of this was taken from the existing DEA and CDC playbooks, why such a sudden change. In short, all evidence points to Kaiser Northern California having made an agreement with the distributor of their controlled substances so that there would not be an interruption in their overall supply. All evidence points to Kaiser having acted to protect their physicians from legal action that would cascade down from the injunction. It is abundantly clear that they accomplished this by agreeing with the distributor that they would mandatorily taper all patients with prescriptions that would likely be marked as "red flags" or "suspicious orders." Your PCP was conveniently taken out of the decision-making loop and those patients in the above category were put into a protocol run by Pharmacy.

Again, perhaps the most harmful part of this settlement was that none of it was aimed and truly supporting patients – especially chronic pain patients who would be most affected by the injunction. To be blunt, it was "a money grab" and a very successful one at that.
https://www.nytimes.com/2014/12/19/us/politics/lawyers-create-big-paydays-by-coaxing-attorneys-general-to-sue-.html

Addendum 3 - THRESHOLDS:

Unlike quotas which are nation-wide production amounts, the injunctions mandate that the distributors now set thresholds. Thresholds are VERY SPECIFIC TO EACH CUSTOMER; each Pharmacy. It limits the limits the total volume of a specific drug family (DEA base code) that a Pharmacy may purchase in a particular period. This total volume is calculated by the Distributor using a statistical algorithm which is not allowed to be shared with the Pharmacy. Once the pharmacy has exceeded its threshold it is unable to obtain additional medications in that specific category. (Norco 5 mg for example). In fact, the Distributor HALTS the distribution of that medication to that specific pharmacy and is required to report this information back to the DEA. Physicians ordering medications, the pharmacists dispensing the medications and obviously the patients have no way of knowing if they are the unlucky ones to have exceeded the threshold. The pharmacy will be out of that medication for the remainder of the time period contracted.

It PROHIBITS the Distributor from shipping 'Suspicious orders" or "Red Flag" orders. This is new. In the past, the pharmacy could explain to a distributor the reason, for example they have an increase in cash customers and still receive the medication. As written in Pain News Network "Algorithms Now Determine If You Get Medication: - "The secret algorithms are effectively deciding your medical treatment. And it is not even based on you as an individual. It's based on how many people at your pharmacy as taking the same medication." "Any orders flagged by the algorithm will automatically be flagged and reported."

4 - How to put in a complaint (California Kaiser Patients)

If you are NOT on disability or Medicare, please call the Department of Managed Health Care at 1-888-466-2219. To date they have ruled favorably in the case of one chronic pain patient (that I am aware of)

If you are on Medicare or Kaiser Senior Advantage NCAL, you must contact Livanta at 866-316-6977 (unfortunately you may not get a satisfactory response from them, but it is worth trying)