U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

[redacted]

APR 2 4 2017

Dear [redacted],

Thank you for your letter dated January 23, 2017, to the Drug Enforcement Administration (DEA). You indicated how the rescheduling of Hydrocodone Combination Products requires you to now undergo expensive random drug testing, limit you to a 90-day maximum supply with no refills, and requires you see your practitioner for each new prescription. The DEA appreciates the opportunity to address your concerns.

Federal law and regulations require that a controlled substance prescription be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner. The Controlled Substances Act (CSA) does not dictate what tools a practitioner must use in assessing each patient's medical condition.

The DEA enforces the CSA and its implementing regulations. However, the DEA does not act as the federal equivalent of a state medical board overseeing the general practice of medicine. State laws and state licensing bodies (such as medical licensing boards) collectively regulate the practice of medicine. You may wish to contact the Pennsylvania State Board of Medicine at (717) 783-1400 and the Pennsylvania State Board of Pharmacy at (717) 783-7156 to inquire whether there are any provisions of state law or regulation that require random drug screenings of patients receiving prescriptions for controlled substances, or how frequently such patients must see the prescribing practitioner.

In regards to your statement on the 90-day maximum supply, federal law and DEA regulations do not impose a specific quantitative minimum or maximum limit on the amount of medication that may be prescribed on a single prescription or the duration of treatment intended with the prescribed controlled substance. Furthermore, the DEA's regulations do not require how often patients are seen by their provider.

In accordance with Federal law "[n]o prescription for a controlled substance in Schedule II may be refilled," Title 21, United States Code, Section 829(a). Although the CSA prohibits refills of prescriptions for Schedule II controlled substances, a practitioner may issue multiple sequential Schedule II prescriptions in order to provide up to a 90-day supply of medication in accordance with Title 21, Code of Federal Regulations, Section 1306.12 (21 C.F.R. § 1306.12). Additional information on this option may be found in the Final Rule title *Issuance of Multiple Prescriptions for Schedule II Controlled Substances*, 72 FR 64921. The DEA's regulations should not be "construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to

CCSF v. Purdue Pharma, et al. 3:18-CV-7591
DEF-MDL-09358
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see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so," 21 C.F.R. § 1306.12(b)(2).

We trust this letter adequately addresses your inquiry. You may obtain a copy of the aforementioned Final Rule on the issuance of multiple prescriptions for Schedule II controlled substances, and the Final Rule titled *Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II.* 79 FR 49661 on the DEA's Diversion Control Division website at www.DEAdiversion.usdoj.gov under Resources. If you have any additional questions on this issue, please contact the Diversion Control Division, Liaison and Policy Section at (202) 307-7297.

Sincerely,

Demetra Ashley
Deputy Assistant Administrator
Diversion Control Division

DC: ✓
CC:
DR:
DCX:
DRX DHS 4/6/17
DRL: 4/6/17
DRLA: 4-6-17
DRLP: 4-6-17
DRLP: OB 4-6 17 (O. Bonilla, 305-7214)

Document: [redacted]
SBF: ODLP-17-0061
DFN: 630-01-C2 (Schedule II) and 601-04-P2 (Pain)

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ODL Subject

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US Department of Justice
Drug Enforcement Administration
Diversion Control Division
950 Pennsylvania Ave., NW
Washington, DC 20530-0001

Dear Sir or Madam:

As I'm sure you are aware, in October of 2014 the DEA rescheduled Hydrocodone Combination Products from Schedule III to Schedule II under the Controlled Substances Act. As a result, Vicodin, the most frequently prescribed opioid in the U.S., is now subject to stricter controls, with the intent of decreasing illegal use and addiction.

I'd like to explain to you the **actual impact** this regulation has had on me, an average citizen who plays absolutely no part in the opiod abuse problem.

I have had fibromyalgia for over 25 years. In that time, I have tried a wide variety of antidepressants, all of the OTC pain medications, and several prescription pain medications. Eventually, a doctor suggested I try Vicodin; out of everything I had tried, this provided the best relief. It does not eliminate the pain, but does suppress it to a degree which allows me to function better and lead a fuller life. For over ten years now I have been managing my pain effectively with Vicodin, and getting annual check-ups from my physician. I take the lowest dose possible, never exceed the prescribed maximum, and have had no side effects. I believe my experience with this drug is a fair representation of the "average" person using Vicodin for effective pain relief.

As a result of this scheduling change, **prescriptions** are now limited to a **90-day maximum supply** with **no refills** allowed, and the **patient must see the doctor to obtain a new prescription.** This means that someone with a legitimate medical need for HCPs must now visit the doctor four times per year, even if there is no change in condition. That means **four times** the amount of time a **doctor** must schedule, **four times** the amount of time a **patient** must spend on doctor visits, and **four times** the amount of **co-pays** for which a patient is responsible. I fail to see how additional office visits would decrease abuse of the drug. Exactly what is a doctor expected to see in **four visits that he/she does not** see in one? The vast majority of physicians are professional, responsible people who give careful consideration to all treatments and prescriptions. These doctors are not contributing to, encouraging, or supporting drug abuse; how is mandating an increase in their workload going to counteract drug abuse??

Medication usage may now be **tracked** in a Prescription Drug Monitoring Program, which is maintained in most states. I understand that would allow physicians to check the list to avoid duplicate prescriptions, but I am not at all comfortable with my personal information being part of a state or national registry. Interestingly, Federal law expressly forbids government from creating a database of gun owners, despite the fact that the number of deaths caused by guns is approximately three times the number caused by opiod drugs. Unfortunately, there is no rich and powerful lobby to protect the rights of patients using HCPs legitimately.

Random drug testing is now **required,** presumably to determine if the amount of HCPs in a patient's system corresponds to the prescribed dosage. Apparently, a disparity would indicate that the patient is either sharing the drug with others or selling it on the street. Since I take the medication on an "as needed" basis, as many people do, I am not confident that the results of drug testing will even be accurate. I have always considered random drug testing to be a violation of my Fourth Amendment rights, and I truly resent the fact that I will be considered **guilty** of drug abuse until my urine sample proves otherwise.

In order to continue to receive the medication that is most effective for my pain management, my doctor's office required me to sign a document agreeing to **random drug testing**; that document also indicated that I would be **responsible for payment** of any amount of lab fees for drug testing that might not be paid by insurance. Some time ago, I submitted a urine sample at the doctor's office for my first random drug test. Several weeks later, while reviewing my Medicare claims on line, I noticed a charge of **$4,801.22** from a toxicology lab for my urine testing! I called the doctor's office to report an error in the billing. The manager of the billing department informed me that the urinalysis for vicodin is "very complicated" and the amount billed was, in fact, **correct**! When I told her Medicare had denied the claim, she assured me that the claim probably needed to be re-submitted and Medicare would, in fact, pay the claim. However, when I received my **Medicare Summary Notice**, it clearly stated that the service was **not approved**, and **no payment** was made. A notation stated "You didn't know this service isn't covered so you don't have to pay. Future services of this type **won't be paid**". While I am relieved that I will not be held responsible for the bill, I am absolutely **appalled** at the amount of the charge and cannot imagine how a urinalysis can be so expensive. It actually makes me wonder if someone is taking advantage of this regulation to line their pockets. Apparently, if I want to continue taking the best medication for my condition, I will have to shell out almost **$5,000** every time my name comes up for a **random drug test!**

Is this really what was intended when the Drug Enforcement Administration changed the HCPs from Schedule III to Schedule II??? I find it questionable that this action will be effective in reducing the amount of opiod abuse, but it seems to be very proficient in forcing **legitimate patients** to stop taking their prescribed medications! I am very angry that **my government** has placed me in a position where, in order to obtain the appropriate medication for my condition, I am required to submit to random drug testing and expected to pay such an outrageous price for the testing! That certainly isn't fair – is it even legal???

REGULATIONS INTENDED TO PROTECT THE PUBLIC SHOULD NOT RESULT IN PUNISHMENT OF THE INNOCENT!!

Sincerely,

[redacted]