U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator *Springfield, VA 22152*

August 23, 2019

see paragraph 24, 25 and 26

IN THE MATTER OF

Pronto Pharmacy, LLC
1461 West Busch Boulevard
Tampa, Florida 33612

Certificate of Registration Number FP2302076

ORDER TO SHOW CAUSE AND
IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Pronto Pharmacy, LLC of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration No. FP2302076, pursuant to 21 U.S.C. § 824(d), because Pronto Pharmacy's continued registration constitutes "an imminent danger to the public health or safety." Notice is also given to afford Pronto Pharmacy an opportunity to show cause before the DEA at the DEA Hearing Facility located at 1550 Crystal Drive, Suite 901, Arlington Virginia, 22202, or a location designated by the Administrative Law Judge, on November 12, 2019, or on such a subsequent date designated by the Administrative Law Judge (if Pronto requests such a hearing), as to why the DEA should not revoke Pronto Pharmacy's Certificate of Registration pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration, or for additional DEA registrations, because Pronto Pharmacy's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f).

As detailed below, this order states the DEA's basis for this Order to Show Cause and Immediate Suspension of Registration, including a ***non-exhaustive summary*** of facts and law at issue, as well as citations to laws and regulations that Pronto Pharmacy has violated (*see* 21 C.F.R. §§ 1301.36(e) and 1301.37(c), which the DEA construes *in pari materia*). In order to preserve Pronto Pharmacy's rights in this proceeding, Pronto Pharmacy must appear in these revocation proceedings by filing a notice of appearance or request for hearing in the manner prescribed by regulations within 30 days from the receipt of this Order.

1. Pronto Pharmacy is registered with the DEA to handle controlled substances in Schedules II through V under Certificate of Registration No. FP2302076. Pronto Pharmacy's registered address is 1461 West Busch Boulevard, Tampa, Florida 33612. Pronto Pharmacy's Certificate of Registration expires by its own terms on March 31, 2022.

2. Pronto Pharmacy is presently licensed in the State of Florida as a "community pharmacy" under license number PH24944. Pronto Pharmacy's state pharmacy license expires by its own terms on February 28, 2021.

3. Norman J. Clement, Sr. is the owner and pharmacist-in-charge at Pronto Pharmacy. Mr. Clement is registered in the State of Florida as a pharmacist under license number PS37644. Mr. Clement's state pharmacist license expires by its own terms on September 30, 2019.

4. As explained in greater detail below, an independent pharmacy expert retained by the DEA has reviewed numerous prescriptions filled by Pronto Pharmacy, and has concluded that Pronto Pharmacy repeatedly issued prescriptions in violation of the minimum practice standards that govern the practice of pharmacy in Florida. Specifically, from at least January 2018 through at least May 2019, Pronto Pharmacy repeatedly filled prescriptions for Schedule II narcotics in the face of obvious red flags of drug abuse and diversion, and, therefore, in violation of both federal and Florida law, including 21 C.F.R. §§ 1306.06 and 1306.04(a), and Fla. Admin. Code r. 64B16-27.810.

5. In addition, the DEA's investigation determined the Pronto Pharmacy was engaged in the "manufacture" of controlled substances, as that term is defined in the Controlled Substances Act, despite not being registered with the DEA as a manufacturer. Manufacturing controlled substances without the appropriate registration is a violation of federal law. *See* 21 U.S.C. § 841(a)(1); 21 C.F.R. § 1301.13(e).

6. As a result, Pronto Pharmacy's DEA Certificate of Registration should be revoked and any pending application should be denied because Pronto Pharmacy has committed such acts as would render its registration inconsistent with the public interest, as that term is defined under the Controlled Substances Act. *See* 21 U.S.C. § 824(a)(4); 21 U.S.C. § 823(f).

IMPROPER DISPENSING

7. A "prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice." 21 C.F.R. § 1306.06. A pharmacist is only permitted to fill a prescription that was "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). Although "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.* Section 1306.04(a) "prohibit[s] a pharmacist from filling a prescription for a controlled substance

THERE IS NO SEPARATE DEA REGISTRATION FOR COMPOUNDING

when she either knows or has reason to know that the prescription was not written for a legitimate medical purpose." *Wheatland Pharmacy*, 78 Fed. Reg. 69,441, 69,445 (2013) (internal quotations and alterations omitted). Section 1306.04(a) "expressly requires pharmacists to identify and resolve suspicions that a prescription is illegitimate." *Trinity Pharmacy II*, 83 Fed. Reg. 7,304, 7,331 (2018).

8. A violation of these federal regulations is a violation of federal law. *See* 21 U.S.C. § 842(a)(l) (making it unlawful to dispense controlled substances in violation of 21 U.S.C. § 829, whose scope is defined in part by 21 C.F.R. §§ 1306.04, 1306.06). Moreover, any attempt to violate these federal regulations is a violation of federal law. *See* 21 U.S.C. § 846. Additionally, the DEA may find that a registrant's DEA certificate of registration is inconsistent with the public interest if the registrant acted carelessly or negligently in handling controlled substances, even if the registrant did not intend to violate the Controlled Substances Act. *See, e.g.*, *The Medicine Shoppe*, 79 Fed. Reg. 59,504, 59,506 (2014) (quoting *Paul J. Caragine, Jr.*, 63 Fed. Reg. 51,592, 51,601 (1998) ("Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify revocation or denial.")).

9. In addition to the federal statutes and regulations, Pronto Pharmacy and its pharmacists must comply with applicable Florida requirements. In particular, Florida pharmacists must "review the patient record and each new and refill prescription presented for dispensing" to identify, among other things, "[o]ver-utilization or under-utilization," "[t]herapeutic duplication," "drug–drug interactions," and "[c]linical abuse/misuse." Fla. Admin. Code r. 64B16-27.810(1). Upon recognizing any of these red flags of abuse or diversion, a Florida pharmacist "shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber." *Id.* r. 64B16-27.810(2). Florida pharmacies must also maintain a patient record system that documents resolution of red flags. *See* Fla. Admin. Code r. 64B16-27.800. Finally, Florida pharmacists must comply with the standards for filling of controlled substance prescriptions. *See* Fla. Admin. Code r. 64B16-27.831 (requiring pharmacists, among other things, to "exercise[] sound professional judgment" and "attempt to work with the patient and the prescriber to assist in determining the validity of the prescription").

10. A Florida pharmacy's failure to comply with Florida's prescription review requirements constitutes a violation of the federal Controlled Substances Act. *See, e.g.*, *Trinity Pharmacy I*, 83 Fed. Reg. 7,304, 7,329 (2018) (citations omitted) ("Thus, [Florida] pharmacists violate Florida law if they fail to identify and resolve the red flags that are part of the prospective drug use review set forth in Rule 64B16-27.810. And if they knowingly fill prescriptions without resolving these red flags during this review, then they violate their corresponding responsibility under 21 C.F.R. § 1306.04(a).").

11. An independent pharmacy expert retained by the DEA reviewed numerous prescriptions filled by Pronto Pharmacy between January 9, 2018 and May 7, 2019, and concluded that Pronto Pharmacy repeatedly issued prescriptions in violation of the minimum practice standards that govern the practice of pharmacy in Florida. The expert opined that the red

flags presented by these prescriptions were so strongly indicative of drug abuse and diversion that they could not have been resolved by a pharmacist acting in the usual course of professional practice. These "red flags" included:

12. **Prescribing of Drug Cocktails:** A common red flag of abuse or diversion is when a physician prescribes "cocktail medications," which are combinations of controlled substances that are widely known to be abused or diverted and that significantly increase a patient's risk of morbidity or overdose. The DEA's expert reviewed numerous prescriptions that were filled by Pronto Pharmacy, and concluded that Pronto Pharmacy regularly dispensed "cocktail medications" without addressing or resolving this red flag. Specifically, the DEA's expert noted that Pronto Pharmacy routinely dispensed high doses of oxycodone along with high doses of benzodiazepines to the same patient. The DEA's expert opined that this combination of drugs is dangerous when used in combination and is well-known by pharmacists as one used by patients abusing and/or diverting controlled substances. Pronto Pharmacy's unlawfully filling of "drug cocktail" medications included the following specific occasions:

dea cleverly redefine common medical procedures in to criminal street language

a. On at least nine occasions between January 25, 2018 and April 12, 2019, Pronto Pharmacy filled prescriptions issued by the same prescriber for Patient A.G. for alprazolam and oxycodone or hydromorphone on the same date. Specifically, Pronto Pharmacy filled prescriptions for hydromorphone and alprazolam issued to Patient A.G. on January 25, 2018; March 1, 2018; April 12, 2018; and May 8 2018. Pronto Pharmacy filled prescriptions for oxycodone and alprazolam issued to Patient A.G. on December 20, 2018; January 17, 2019; February 14, 2019; March 20, 2019; and April 12, 2019.

b. On at least five occasions between January 29, 2018 and April 22, 2019, Pronto Pharmacy filled prescriptions issued by the same prescriber for Patient B.S. for alprazolam and oxycodone or hydromorphone on the same date. Specifically, Pronto Pharmacy filled prescriptions for hydromorphone and alprazolam issued to Patient B.S. on January 29, 2018 and May 22, 2018. Pronto Pharmacy filled prescriptions for oxycodone and alprazolam issued to Patient B.S. on December 20, 2018; February 28, 2019; and March 26, 2019.

c. On at least three occasions between September 14, 2018 and January 16, 2019, Pronto Pharmacy filled prescriptions issued by the same prescriber for Patient N.B. for alprazolam and oxycodone or hydromorphone on the same date. Specifically, Pronto Pharmacy filled prescriptions for hydromorphone and alprazolam issued to Patient N.B. September 14, 2018. Pronto Pharmacy filled prescriptions for oxycodone and alprazolam issued to Patient N.B. on December 20, 2018 and January 16, 2019.

d. On at least three occasions between March 6, 2018 and July 12, 2018,

Pronto Pharmacy filled prescriptions issued by the same prescriber for Patient C.R. for alprazolam and oxycodone on the same date. Specifically, Pronto Pharmacy filled prescriptions for oxycodone and alprazolam issued to Patient C.R. on March 6, 2018; April 19, 2018; and July 12, 2018.

e. On at least five occasions between January 25, 2018 and May 16, 2018, Pronto Pharmacy filled prescriptions issued by the same prescriber for Patient J.M. for alprazolam and oxycodone on the same date. Specifically, Pronto Pharmacy filled prescriptions for oxycodone and alprazolam issued to Patient J.M. on January 25, 2018; March 1, 2018; April 4, 2018; April 19, 2018; and May 16, 2018.

13. **Early Refills of Controlled Substance Prescriptions**: The DEA's expert opined that, under the binding minimum norms that govern the practice of pharmacies, filling prescriptions significantly or consistently early is a well-known red flag of diversion or abuse of controlled substances. A prescription is considered to be filled "early" when the patient still has medication remaining from a previous prescription. The DEA's expert reviewed Pronto Pharmacy's dispensing log and identified numerous instances in which Pronto Pharmacy filled a patient's prescription early. The DEA's expert opined that a reasonable and prudent pharmacist would not fill so many controlled substance prescriptions early and that a pharmacist who was properly exercising his corresponding responsibility would have recognized this and refused to fill most of these prescriptions. Pronto Pharmacy's early filling of controlled substances prescriptions included the following specific occasions:

opinion based on what fact

SO CALLED DEA EXPERT DOESN'T EXAM PATIENT RECORDS OR CONDUCTS NO PHYSICAL EXAM OF PATIENT.

C-2 MEDS ARE NOT REFILLIABLE

a. **Patient A.H.**: On January 22, 2019, Pronto Pharmacy filled a prescription for Patient A.H. for a 30 day supply of hydromorphone 8 mg tablets. Pronto Pharmacy filled additional prescriptions for Patient A.H. for 30 day supplies of hydromorphone 8 mg tablets on February 15, 2019 (six days early); February 27, 2019 (18 days early); and March 14, 2019 (15 days early).

b. **Patient M.M.**: On January 3, 2019, Pronto Pharmacy filled a prescription for Patient M.M. for a 28 day supply of hydromorphone 8 mg tablets. Pronto Pharmacy filled additional prescriptions for hydromorphone 8 mg tablets for Patient M.M. for a 30 day supply on January 24, 2019 (seven days early); a 30 day supply on February 19, 2019 (four days early); and a 28 day supply on March 15, 2019 (six days early).

c. **Patient J.D.**: On May 10, 2018, Pronto Pharmacy filled a prescription for Patient J.D. for a 30 day supply of hydromorphone HCL powder. Pronto Pharmacy filled additional prescriptions for Patient J.D. for 30 day supplies of hydromorphone HCL powder on May 30, 2018 (10 days early); June 15, 2018 (14 days early); and June 30, 2018 (15 days early).

d. **Patient R.G.**: On January 29, 2018, Pronto Pharmacy filled prescriptions for Patient R.G. for a 30 day supply of oxycodone HCL powder and a 30 day supply of alprazolam 2 mg tablets. Pronto Pharmacy filled additional prescriptions for 30 day supplies of oxycodone HCL powder and alprazolam 2 mg tablets for Patient R.G. on February 21, 2018 (seven days early); March 19, 2018 (four days early); April 17, 2018 (one day early); and May 8, 2018 (nine days early).

e. **Patient R. L.**: On February 1, 2018, Pronto Pharmacy filled a prescription for Patient R.L. for a 30 day supply of hydromorphone HCL powder. Pronto Pharmacy filled additional prescriptions for hydromorphone HCL powder to Patient R.L. on a 30 day supply on February 26, 2018 (five days early); a 29 day supply on March 22, 2018 (six days early); a 30 day supply on April 17, 2018 (three days early); and a 30 day supply on May 11, 2018 (six days early).

14. **Excessive Dispensing of High Strength Controlled Substances**: The DEA's expert opined that it is a well-known red flag that the dispensing of a disproportionate number of prescriptions for the highest strength available for a particular controlled substance is a sign of illicit activity. The DEA's expert noted that virtually all of the prescriptions for oxycodone and hydromorphone that Pronto Pharmacy "compounded" during that time frame were for oxycodone 30 mg immediate release and hydromorphone 8 mg immediate release (the highest strengths for these controlled substances). In addition, the DEA's expert noted that, between January 11, 2018 and July 17, 2018, 100 percent of the oxycodone tablet prescriptions and 87 percent of the hydromorphone tablet prescriptions (approximately 44 prescriptions total) issued by a particular prescriber were for the highest strength available for those controlled substances. The DEA's expert opined that a pharmacist who was properly exercising his corresponding responsibility would have recognized this and refused to fill most of these prescriptions.

15. **Patients Travelling Long Distances to Fill Prescriptions at Pronto Pharmacy**: The DEA's expert opined that it can be a red flag of abuse and diversion if a patient travels a significant distance to a specific pharmacy, especially if the patient also travels a significant distance to a particular prescriber. Numerous Pronto Pharmacy customers traveled significant distances to obtain and fill their prescriptions. For example, between September 10, 2018 and May 6, 2019, Pronto Pharmacy filled:

1. HOW DO THEY ACCOUNT FOR MAIL ORDER DISTANCE ??

a. 86 prescriptions for patients with addresses in Cape Coral, Florida, which is approximately 140 miles from Pronto Pharmacy;

b. 145 prescriptions for patients with addresses in Fort Myers, Florida, which is approximately 130 miles from Pronto Pharmacy;

c. 41 prescriptions for patients with addresses in Lehigh Acres, Florida, which is approximately 140 miles from Pronto Pharmacy;

2. DOES DISTANCE SOLELY APPLY TO PHARMACIES AND NOT TO HOSPITALS PHYSICIAN AND DENTAL PRACTICES ??

4. People get their medications from Canada are they criminals or the pharmacy whom fill these prescriptions

3. in all these case patients have a legitimate doctors prescription then how does distant equates to criminallity??

d. 15 prescriptions for patients with addresses in Immokalee, Florida, which is approximately 150 miles from Pronto Pharmacy;

e. 15 prescriptions for patients with addresses in Naples, Florida, which is approximately 170 miles from Pronto Pharmacy; and

f. 11 prescriptions for patients with addresses in Opa-locka, Florida, which is approximately 270 miles from Pronto Pharmacy.

16. The DEA's expert further noted that Pronto Pharmacy was also many miles from the medical practices of the top prescribers whose prescriptions were filled at Pronto Pharmacy. For example, between September 10, 2018 and May 6, 2019, over 75 percent of the prescriptions for controlled substances filled by Pronto Pharmacy were issued by prescribers whose medical practices were located more than 150 miles away from Pronto Pharmacy.

17. DEA's expert opined that both patients travelling long distances from their residences and patients travelling long distances from the medical practices of the prescribers to have their prescriptions filled are significant red flags that the prescriptions being filled by Pronto Pharmacy were being abused and/or diverted and that a pharmacist who was properly exercising his corresponding responsibility would have recognized this and refused to fill most of these prescriptions.

including credit, debit payments

What is excessive cash are there some percentage or limitation???

8. **Excessive Cash Payments:** The DEA's expert opined that cash payments can be a red flag of abuse or diversion because patients typically have to pay very high prices for drugs that are not covered by insurance. The DEA's expert noted that, on average, approximately 11 percent of all prescriptions filled by independently owned pharmacies in 2018 were paid for in cash nationally. The DEA's expert noted that over 90 percent of the prescriptions for oxycodone 30 mg and hydromorphone 8 mg filled by Pronto Pharmacy were paid for with cash. The DEA's expert opined that this is a significant red flag that the prescriptions being filled by Pronto Pharmacy were being abused and/or diverted and that a pharmacist who was properly exercising his corresponding responsibility would have recognized this and refused to fill most of these prescriptions.

iS there a law in America against taking cash??

19. The DEA's expert reviewed the above-referenced prescriptions and concluded that they presented numerous red flags that were highly indicative of abuse and diversion. These red flags could not have been resolved by a pharmacist acting in the usual course of professional practice, and, therefore, each prescription was filled outside the standard of care in Florida. Accordingly, these prescriptions were filled in violation of federal and state law. *See* 21 U.S.C. § 842(a)(l); 21 C.F.R. § 1306.04(a); Fla. Admin. Code r. 64B16-27.810.

SO A DEA CERTIFICATE RESTRICTS TAKING CASH FROM PATIENTS ???

paragraph 18 The DEA expert's opinion is further serious flawed because their 90 percent included THOSE PATIENT WHO PAY BY CREDIT OR DEBIT CARD??? THIS IS A judgemental Bias.

PHYSICIAN'S OFFICE INDICATES WEATHER PATIENT IN UNINSURED!!!! ON EACH PRESCRIPTION!!!!!

ILLEGAL MANUFACTURING

20. Under the Controlled Substances Act, a registrant is required to maintain a separate and independent registration for each of the "controlled substances activities" that it wishes to engage in. *See* 21 C.F.R. § 1301.13(e) ("Any person who engaged in more than one group of independent activities shall obtain a separate registration for each group of activities, except as provided in this paragraph under coincident activities.")

21. Pronto Pharmacy is registered with the DEA to engage in "dispensing." *See* 21 C.F.R. § 1301.13(e)(1)(iv). The Controlled Substances Act defines "dispensing" as the "deliver[y] of a controlled substance to an ultimate user or research subject by, or pursuant to the law order of, a practitioner, including . . . the packaging, labeling, or compounding necessary to prepare the substance of such delivery." 21 U.S.C. § 802(11).

22. The Controlled Substances Act defines "manufacturing" as "the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable state or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice." 21 U.S.C. § 802(15).

*form 222****

we are in conformity with FDA and Florida law

23. In order to be exempt from the definition of a manufacturer under the CSA, "a DEA practitioner registrant must be engaged in compounding controlled substances on an individual patient basis. That is, a pharmacy must receive a prescription for a specific patient from a physician or other individual practitioner and must deliver or dispense that medication to the patient." *Wedgewood Village Pharmacy*, 71 Fed. Reg. 16,593, 16,595 (2006); *see also Thompson v. Western States Medical Center*, 535 U.S. 357, 361 (2002) ("Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient.").

we are compounding

24. A person that is not "preparing or compounding medications containing controlled substances on an individualized patient basis" is engaged in "manufacturing" controlled substances as that term is defined in the Controlled Substances Act and must be registered with the DEA as a manufacturer. *Wedgewood Village Pharmacy*, 71 Fed. Reg. 16,593, 16,595 (2006).

we are compounding

25. The DEA's investigation concluded that Pronto Pharmacy is engaged in "manufacturing" rather than "compounding" controlled substances, as those terms are used in the CSA.

DEA INVESTIGATOR CONCLUDED THE PRONTO PHARMACY WAS "MANUFACTURING" RATHER THAN "COMPOUNDING"

" is not preparing or compounding"

HOWEVER DEA EXPERT OPINS IN PARAGRAPH 26 PRONTO PHARMACY WAS COMPOUNDING

opinion based on what fact?? since when does an opinion support a raid

26. The DEA's independent pharmacy expert reviewed purchasing and dispensing data for Pronto Pharmacy between January 2018 and May 2019. The DEA's expert opined that Pronto Pharmacy was "compounding" an unreasonably large quantity of oxycodone and hydromorphone capsules.

a. The DEA's expert opined that "compounding" should be limited to individual patients who cannot be treated with a commercially available medication for an individualized reason, such as an allergy to a particular ingredient. The DEA's expert further opined that such allergies are rare and, as a result, "compounded" medications should not form a significant part of a pharmacy's dispensing. The DEA's expert opined that Pronto Pharmacy was "compounding" medication in quantities that far exceeded the amounts that would be expected from a legitimate retail pharmacy.

DEA EXPERT says 5 times Pronto compounded

b. The DEA's expert noted that a compounded capsule form of a controlled substance poses a heighten risk of abuse and/or diversion because capsules can more easily be converted into an injectable form (a preferred method of abuse) than a tablet can. As a result, the DEA's expert opined that a controlled substance should not be compounded when there is a commercially available alternative that poses a lower risk of abuse and/or diversion. The DEA's expert noted that both oxycodone 30 mg and hydromorphone 8 mg tablets are readily available from multiple commercial suppliers. As a result, the DEA's expert opined that Pronto Pharmacy was not legitimately "compounding" these medications consistent with the standard of practice at a retail pharmacy.

27. The DEA's expert's opinion was consistent with previous statements made by Mr. Clement, Pronto Pharmacy's owner and pharmacist-in-charge, to DEA investigators. On or about May 1, 2012, DEA investigators conducted an interview of Mr. Clement. During that interview:

the May 1st big lye:
1.meeting never took place

2. May 1st was on Tuesday 2012***

a. Mr. Clement told DEA investigators that Pronto Pharmacy "manufactured" controlled substances (specifically oxycodone and hydromorphone) because the capsules manufactured by Pronto Pharmacy were cheaper to produce and could be sold for the same price as the tablets that could be bought from other manufacturers (*i.e.*, it would allow Pronto Pharmacy to increase its profit margin).

b. Mr. Clement acknowledged that Pronto Pharmacy was able to purchase these controlled substances in tablet form from manufacturers, but emphasized that Pronto Pharmacy's manufactured product was just as good as the tablets while cheaper to produce.

pronto pharmacy is not a manufacturer but compounds under the guidelines of FDA 503A.

All alleges statements from N.J. Clement made 7 years ago in May of 2012**

All allege statements made by N.J.Clement occured
May 1, 2012

c. Mr. Clement explained the manufacturing process. Specifically, he noted that Pronto Pharmacy would manufacture as many as 3,000 capsules at one time. Mr. Clement explained to the DEA investigators that he manufactured controlled substances based on projected demand and that it would not be cost effective to wait to receive a prescription or to prepare the controlled substances on an individualized patient basis. Specifically, Mr. Clement stated: "I can manufacture. I'm a pharmacist. I can make this."

28. In sum, by bulk producing controlled substances—including oxycodone and hydromorphone capsules—without a specific prescription and without preparing those controlled substances on an individualized patient basis, Pronto Pharmacy is engaged in "manufacturing" controlled substances, as that term is use in the CSA. Because Pronto Pharmacy is not registered with the DEA as a "manufacturer," such manufacturing is a violation of federal law. *See* 21 U.S.C. § 841(a)(1); 21 C.F.R. § 1301.13(e).

2012**

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(f) and 824(a)(4), it is my preliminary finding that Pronto Pharmacy's continued registration is inconsistent with the public interest. It is my preliminary finding that Pronto Pharmacy repeatedly dispensed controlled substances without attempting to address or resolve clear red flags of abuse and diversion, which is inconsistent with the public interest. It is also my preliminary finding, significantly in light of the rampant and deadly problem of prescription controlled substance abuse, that Pronto Pharmacy's continued registration during the pendency of these proceedings would constitute "an imminent danger to the public health or safety" because of the substantial likelihood that Pronto Pharmacy will continue to unlawfully prescribe controlled substances, thereby allowing the diversion of controlled substances, unless Pronto Pharmacy's DEA Certificate of Registration is suspended. Under the facts and circumstances described herein, it is my conclusion that Pronto Pharmacy's continued registration while these proceedings are pending constitutes "an imminent danger to the public health or safety." *See* 21 U.S.C. § 824(d). Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration No. FP2302076 is hereby suspended, effective immediately. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Pronto Pharmacy possesses pursuant to the registration which I have herein suspended. The said Agents and Investigators are also directed to take into their possession Pronto Pharmacy DEA Certificate of Registration FP2302076 and any unused order forms.

THE following procedures are available to Pronto Pharmacy in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Pronto Pharmacy may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Pronto Pharmacy fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Pronto Pharmacy may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).

3. Should Pronto Pharmacy decline to file a request for a hearing, or should Pronto Pharmacy request a hearing and then fail to appear at the designated hearing, Pronto Pharmacy shall be deemed to have waived the right to a hearing and the DEA may cancel such hearing, and I may enter my final order in this matter without a hearing based upon the evidence presented to me. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Requests for hearing should be filed by email with the Office of Administrative Law Judges at the following address: ECF-DEA@usdoj.gov, with a copy simultaneously provided to the Government at the following address: DEA.Registration.Litigation@usdoj.gov. Other correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152. A copy of the same shall also be served on Government counsel John Beerbower and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrissette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45.

Uttam Dhillon
Acting Administrator
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
John E. Beerbower, Counsel for the Government

REQUEST FOR HEARING

Any person desiring a hearing with request to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters
Office of the Administrative Law Judges
Hearing Clerk
8701 Morrissette Drive
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

(A) [State with particularity the interest of the person in the proceeding.]

(B) [State with particularity the objections or issues, if any concerning which the person desires to be heard.]

(C) [State briefly the position of the person with regard to the particular objections or issues.]

(D) [Name (either registrant, applicant, or attorney), address (including street address, city, state and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant, or attorney]

Note: Pursuant to 21 C.F.R. § 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.