DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Medical Technology Enterprise Consortium

Notice is hereby given that, on September 29, 2017, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Medical Technology Enterprise Consortium (''MTEC'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, 2C4 Technologies, Inc., San Antonio, TX; Actuated Medical, Inc., Bellefonte, PA; American Type Culture Collection (ATCC Federal Solutions), Manassas, VA; Amethyst Technologies, LLC, Baltimore, MD; Anu Life Sciences, Sunrise, FL; Arteriocyte, Inc. d/b/a/Compass Biomedical, Hopkinton, MA; Charles River Analytics, Inc., Cambridge, MA; Chimerix, Inc., Durham, NC; Cole Engineering Services, Inc., Orlando, FL; Corvid Technologies, Mooresville, NC; Daxor Corporation, New York, NY; Elemance, LLC, Clemmons, NC; Emergent BioSolutions, Gaithersburg, MD; Human Biomed, Inc., South Burlington, VT; L–3 Applied Technologies, Inc., San Diego, CA; LifeLink Foundation, Inc., Tampa, FL; MalarVx, Inc., Seattle, WA; Manzanita Pharmaceuticals, Inc., Woodside, CA; Medtronic, Minneapolis, MN; Melinta Therapeutics, Inc., New Haven, CT; Neuroplast BV, Maastricht, NETHERLANDS; Platelet BioGenesis, Inc., Boston, MA; RegeniSource LLC, San Antonio, TX; Remedor Biomed Ltd., Nazareth lllit, ISRAEL; Roccor, LLC, Longmont, CO; Soar Technology, Inc., Ann Arbor, MI; SynDaver Labs, Tampa, FL; The Board of Supervisors of Louisiana State University and Agricultural & Mechanical College herein represented by Louisiana State University Health Sciences Center in New Orleans (LSUHSC), New Orleans, LA; The Medical College of Wisconsin, Inc., Milwaukee, WI; The Metis Foundation, San Antonio, TX; University of Iowa, Iowa city, IA; University of Maryland, College Park, MD; Vcom3D, Inc., Orlando, FL, and Vivacelle Bio, Inc., Chicago, IL have been added as parties to this venture.

Also, Applied Medical Device Institute (aMDI)—Grand Valley State University, Grand Rapids, MI; Aptus, LLC, Clemson, SC; Ellipsis Technologies, Inc., Greenville, SC; Johns Hopkins University, Baltimore, MD; Longeveron LLC, Miami, FL; Lovelace Biomedical and Environmental Research Institute, Albuquerque, NM; MicroCures, Inc., Santa Cruz, CA; New York Institute of Technology, Old Westbury, NY; NGT–VC 2012 Limited Partnership (NGT3), Nazareth, ISRAEL; and Otologic Pharmaceutics Inc., Oklahoma City, OK, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and MTEC intends to file additional written notifications disclosing all changes in membership.

On May 9, 2014, MTEC filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 9, 2014 (79 FR 32999).

The last notification was filed with the Department on June 23, 2017. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 15, 2017(82 FR 38708).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

ChipRX, L.L.C., d/b/a City Center Pharmacy; Decision and Order

On August 19, 2016, the former Acting Administrator issued an Order to Show Cause and Immediate Suspension of Registration to ChipRX, L.L.C., d/b/a City Center Pharmacy (hereinafter, Registrant), of Hamlin, West Virginia. The Show Cause Order proposed the revocation of Registrant's DEA Certificate of Registration and the denial of any pending application to renew or modify its registration, on the ground that its ''continued registration is inconsistent with the public interest.'' Show Cause Order, at 1 (citing 21 U.S.C. 824(a)(4) and 823(f)).

As to the Agency's jurisdiction, the Show Cause Order alleged that Registrant is registered as a pharmacy with authority to dispense schedule II–V controlled substances under Registration No. FC3015915, at the registered address of 8119 Court Avenue, Hamlin, West Virginia. *Id.* at 1. The Order alleged that this registration was due to expire on August 31, 2017. *Id.*

As to the substantive grounds for the proceeding, the Show Cause Order alleged that Registrant is owned by George ''Chip'' Chapman and Summer Chapman, and that George Chapman is Registrant's Pharmacist-in-Charge (PIC). *Id.* The Show Cause Order alleged that on June 30, 2016, DEA executed an Administrative Inspection Warrant (AIW) at Registrant based on ''tips that PIC Chapman was frequently impaired and was unlawfully removing controlled substances from the pharmacy.'' *Id.* at 2. The Order then alleged that during the inspection, DEA personnel interviewed PIC Chapman and other pharmacy employees. *Id.*

With respect to the interview of PIC Chapman, the Show Cause Order alleged that he made various material false statements to the Investigators. *Id.* These included minimizing the quantity of oxycodone and hydrocodone that had been lost ''in the last year,'' stating that he had failed to reported all but one of the instances in which these drugs were ''lost'' because they were '''not significant' losses,'' by denying that he knew ''anything further about the nature of the pharmacy's losses'' while ''claim[ing] that he was not abusing prescriptions drugs,'' and stating ''that many of his per diem or fill-in pharmacists were previous drug abusers.'' *Id.*

The Show Cause Order then alleged that in a subsequent interview conducted on July 22, 2016, Chapman ''admitted that during the past year, he diverted oxycodone or hydrocodone pills equivalent to '200–300 mg every day,' a total of approximately 25,000 pills.'' *Id.* at 3. The Order also alleged that ''Chapman admitted that he routinely falsified inventory records'' and that he ''shredded invoice and supplier records, including DEA 222 forms and electronic Controlled Substances Ordering System ('CSOS') records.'' *Id.* The Order further alleged that ''Chapman admitted that he had relapsed,'' and told ''DEA [I]nvestigators that he 'couldn't wait' for'' the expiration of the Memorandum of Agreement (MOA) which he had previously entered into with the Agency ''so he could begin diverting . . . drugs to feed his addiction.'' *Id.* The Order then alleged that Chapman admitted to

abusing cocaine for the past two years. *Id.*[1]

The Show Cause Order also alleged that from January 12, 2015[2] to the ''present,'' Registrant's owner had committed numerous violations of the Controlled Substances Act. First, the Order alleged that Chapman ''unlawfully removed pills from the [p]harmacy.'' *Id.* (citing 21 U.S.C. 829(a) & (b), 841(a)(1), and 844(a)). Second, the Order alleged that Chapman ''us[ed] the [p]harmacy to fuel his own drug addiction,'' in that he ordered controlled substances other than in ''the conduct of lawful business or professional practice.'' *Id.* (citing 21 U.S.C. 828(e)). Third, the Order alleged that Registrant ''failed to report losses as required'' by DEA regulations. *Id.* (citing 21 CFR 1301.76(b)). Fourth, the Order alleged that Registrant ''has failed to maintain effective controls against diversion and theft.'' *Id.* (citing 21 CFR 1307.71).[3] Fifth, the Order alleged that Registrant ''has failed to maintain accurate inventory controls'' in that ''Chapman routinely manipulated computer inventory records.'' *Id.* at 4 (citing 21 U.S.C. 827(a) & (b); 842(a)(5)). Sixth, the Order alleged that Registrant ''has routinely destroyed controlled substance ordering records'' and that ''Chapman regularly shredded invoices . . . from its suppliers to conceal the extent of his diversion.'' *Id.* (citing 21 CFR 1305.17 and 1305.27). Seventh, the Order alleged that on June 30, 2016, Registrant ''provided a [c]losing [i]nventory certifying that it was complete and accurate,'' but that ''[b]ased on . . . Chapman's admissions, this report was not complete or accurate.'' *Id.* (citing 21 U.S.C. 824(a)(4)(A), 21 CFR 1304.03, 1304.04, 1304.11, and 1304.21).

In addition to the above, the Show Cause Order alleged that Chapman ''repeatedly deleted [p]harmacy video surveillance footage of his unlawful removal of controlled substances from the [p]harmacy,'' that ''Chapman frequently exhibits signs of impairment or intoxication while at work,'' and that ''[w]hile impaired, [he] has incorrectly filled prescriptions.'' *Id.* The Order also alleged that ''[d]uring the course of the last year, [p]harmacy personnel have repeatedly identified significant losses in routine pill counts,'' including a loss of 100 oxycodone pills ''in the week preceding [the] June 30, 2016'' inspection. *Id.* The Order further alleged that ''[t]hese losses occurred on a regular basis'' and involved ''oxycodone, hydrocodone, oxymorphone, and ADHD pills,'' and that ''[t]hese losses were consistently reported to . . . Chapman.'' *Id.*

Next, the Show Cause Order alleged that ''[d]espite knowing . . . that DEA was actively investigating'' his pharmacy, Chapman diverted oxycodone and other drugs ''on least [five] occasions between June 30, 2016 and August 5, 2016.'' *Id.* at 5. Specifically, the Order alleged that ''[b]etween July 15 and July 18, 2016, Chapman took 64 oxycodone pills,'' that ''[o]n July 21, 2016, Chapman removed oxycodone pills from a locked cabinet and placed an unknown number of loose pills in his pocket,'' that ''[o]n July 23, 2016, Chapman entered the [p]harmacy outside of store hours and took a 100 count bottle of oxycodone pills,'' and that ''[o]n August 3, 2016, Chapman again took oxycodone pills from the [p]harmacy['s] stock.'' *Id.* The Order also alleged that ''[a]t least two of these incidents are recorded on video obtained by DEA.'' *Id.*

The Show Cause Order further alleged that ''Chapman was hospitalized for complications related to overdose on at least three recent occasions, including . . . on approximately April 6, 2016, June 17, 2016, and July 18, 2016.'' *Id.* The Order alleged that on or about these dates, Chapman ''tested positive'' for controlled substances which included oxycodone at each test (as well as cocaine on July 18, 2016), even though records from the West Virginia Prescription Monitoring Program ''indicate that [he] did not receive any prescription for oxycodone or cocaine during the last year.'' *Id.*

Finally, the Show Cause Order alleged that ''[o]ther [p]harmacy personnel have seen . . . Chapman using marijuana via [a] vaporizer while working at'' Registrant. *Id.* After again alleging that Chapman admitted to ''abus[ing] cocaine during the course of the last two years,'' the Order alleged that ''Chapman's possession of illicit controlled substances violates 21 U.S.C. 844(a).'' *Id.*

Based on his ''preliminary finding that controlled substances were diverted from [Registrant] on numerous occasions in connection with serious misconduct involving concealment, falsification of inventory records, circumvention of security controls, and misuse of [its] [r]egistration to order controlled substances for purposes other than the conduct of lawful business or professional practice,'' the former Acting Administrator concluded that Registrant's registration ''is inconsistent with the public interest.'' *Id.* at 6. The former Acting Administrator also made the ''preliminary finding'' that Registrant's ''continued registration during the pendency of these proceedings would constitute an imminent danger to the public health and safety because of the substantial likelihood . . . that death, serious bodily harm or abuse of controlled substances will occur in the absence of this suspension.'' *Id.* The former Acting Administrator thus concluded that Registrant's continued registration during the pendency of the proceeding ''constitutes an imminent danger to the public health and safety'' and suspended its registration ''effective immediately.'' *Id.* (citing 21 U.S.C. 824(d)). The former Acting Administrator's Order also authorized the seizure or placement under seal of Registrant's controlled substances. *Id.*

The Show Cause Order notified Registrant of its right to request a hearing on the allegations or to submit a written statement while waiving its right to a hearing, the procedures for electing either option, and the consequence of failing to elect either option. *Id.* (citing 21 CFR 1301.43). On the same day it was issued, a DEA Diversion Investigator personally served the Order to Show Cause and Immediate Suspension of Registration on Registrant's pharmacy manager at which time the Investigators took custody of Registrant's controlled substances and Certificate of Registration. GX 3, at 2 ¶ 7.

According to the Government, since the date of service of the Order, Registrant has neither requested a hearing nor submitted a written statement while waiving its right to a hearing. Request for Final Agency Action, at 1–2. Based on the Government's representation, I find that more than 30 days have now passed and Registrant has neither requested a hearing nor submitted a written statement while waiving its right to a hearing. I therefore find that Registrant has waived its right to a hearing or to submit a written statement and issue this Decision and Order based on reliable and probative evidence submitted by the Government. *See* 21 CFR 1301.43(e). I make the following findings.

Findings of Fact

Registrant is a limited liability company organized under the laws of West Virginia; it owns and operates City Center Pharmacy, a retail pharmacy located at 8119 Court Avenue, Hamlin, West Virginia. GX1; GX 3, at 1.

[1] The Show Cause Order also alleged that during the June 30, 2016 interview, Chapman admitted that he regularly used marijuana. Show Cause Order, at 3.

[2] The Government alleged that the MOA expired on January 12, 2015. Show Cause Order, at 3.

[3] The correct citation is to 21 CFR 1301.71(a).

According to the records of the West Virginia Secretary of State, George Chapman and his wife Summer Chapman are member-officers of the company. GX 3, Appendix 2, at 2. George Chapman is the Pharmacist-in-Charge (PIC). GX 3, at 2; *see also id.* at Appendix 3.

Registrant previously held DEA Certificate of Registration No. FC3015915, pursuant to which it was authorized to dispense controlled substances in schedules II through V as a retail pharmacy at the above address. GX 1. This registration expired on August 31, 2017. *Id.* According to the registration records of the Agency (of which I take official notice, *see* 5 U.S.C. 556(e)), Registrant did not file a renewal application. However, according to the declaration of the Diversion Investigator, upon service of the Immediate Suspension Order, the Government took custody of Registrant's controlled substances. GX 3, at 1.

In 2009, Chapman, who was then employed at a hospital pharmacy, was convicted of a misdemeanor offense of embezzling controlled substances from his employer and placed on probation.[4] GX 3, Appendix 1, at 1–2. Chapman, who pled guilty to the charge, was placed on probation for a period of one year. *Id.* at 1. Thereafter, Chapman applied for a retail pharmacy registration in schedules II through V, and was allowed to enter into an MOA, which became effective on January 12, 2012, and remained in effect for a period of three years, after which Registrant's Registration became unrestricted. GX 3, Appendix 3, at 1–4.

The Investigation of Registrant

In June 2016, a DEA Diversion Investigator (DI) assigned to the Charleston, West Virginia Resident Office received ''multiple tips'' that George Chapman ''often appeared impaired at work.'' GX 3, at 2. The DI initiated an investigation and determined that Chapman had previously pled guilty in state court ''to embezzling and abusing approximately 800 hydrocodone and oxycodone pills from approximately June through October 2009.'' *Id.* He also determined that Chapman had, as a condition of obtaining a registration for the pharmacy, entered into an MOA with the Agency. *Id.*

The DI obtained an Administrative Inspection Warrant (AIW), and on June 30, 2016, he, accompanied by other Investigators, executed the AIW at Registrant. *Id.* According to the DI, ''[t]he [p]harmacy's inventory records were found to be so incomplete and unreliable that no formal audit using the . . . records could be completed.'' *Id.* The DI further stated that during the inspection, Chapman ''admitted that [the] electronic inventory records had been repeatedly manipulated'' and the ''records were otherwise so disorganized that conducting a reliable on-site audit was impossible.'' *Id.*

The DI further stated that during the inspection, ''several [p]harmacy [employees] uniformly reported to [him] that . . . Chapman regularly came to work impaired'' and ''[s]everal employees also reported that pills were regularly missing from the [p]harmacy during the last year.'' *Id.*

One pharmacy employee told the DI that on occasions when a ''per diem [p]harmacist'' was working at Registrant, Chapman came to the pharmacy, ''asked to use'' the employee's computer, after which he ''open[ed] the locked cabinet'' in which the oxycodone was kept and [took] a 100 count wholesale bottle of oxycodone 15 mg'' out of the cabinet, then ''went to his office'' and subsequently ''left the pharmacy.'' *Id.* at 3. The employee told the DI that she subsequently opened the cabinet to confirm that the bottle was missing; she also ''attempted to review the surveillance video'' only to find that ''it had been deleted.'' *Id.* The employee also told the DI that she checked the computer inventory records and found that 100 pills of oxycodone 15 mg had been removed from the count of drugs ''on hand.'' *Id.*

The same employee told the DI ''that the [p]harmacy regularly experiences inventory losses'' and had been experiencing them ''for more than a year.'' *Id.* The employee told the DI that on the very day that the AIW was executed, her comparison of the computer inventory and the actual count of drugs on hand found that 107 dosage units of hydrocodone 10 mg were missing. *Id.* The employee also told the DI that in the weeks prior to the AIW, one bottle of oxycodone 20 mg and one bottle of oxycodone 15 mg went missing. *Id.*

The employee further told the DI that Chapman was impaired at work on an almost daily basis and that he would ''spend the majority of his day asleep in his office.'' *Id.* She also told the DI of an instance in which Chapman ''had incorrectly filled a prescription'' which she corrected and that ''she saw Chapman using a vaporizer at work to smoke marijuana regularly.'' *Id.*

According to the DI, following the AIW, the same employee ''reported to [him] multiple other instances where . . . Chapman had stolen oxycodone'' from Registrant; the employee stated that these incidents occurred on July 18 and 23, as well as August 3, 2016. *Id.* The employee also took a photograph showing Chapman ''passed out at his desk on July 18, a day when he was . . . taken to the hospital'' because he overdosed. *Id.* at 3–4. According to the employee, on that day, ''64 oxycodone pills were missing compared with a physical pill count conducted on July 15, 2017.'' *Id.* at 4. The DI subsequently subpoenaed the photo; the Government submitted the photo as part of the evidentiary record. *Id.* at 3; *see also* Appendix 4.

During the AIW, the DI also interviewed Chapman. GX 3, at 3. During the interview, Chapman stated that the ''[p]harmacy had destroyed approximately 70 Percocet pills sometime in the past and that . . . he had adjusted the 'inventory book' so that the records would reflect the physical inventory.'' *Id.* Chapman admitted, however, that he did not report ''this shortage'' to DEA. *Id.* He also maintained he had ''attempted to report a loss of 100 pills to DEA but did not attempt to report other losses either to DEA or local law enforcement because he considered them 'not significant.' '' *Id.* Chapman further represented ''that 10–15 oxycodone or hydrocodone pills would be missing from the [p]harmacy . . . perhaps 15–20 times in the prior year'' and that ''there was a total loss of perhaps 300 oxycodone and hydrocodone pills.'' *Id.* at 3–4. Chapman stated that ''on those occasions when he found a pill shortage in the physical inventory as compared with the computer records, he adjusted the computer inventory to reflect the losses.'' *Id.* However, ''Chapman admitted that he did not report a loss for any of these losses.'' *Id.* at 4.

During the interview, ''Chapman denied that he was abusing prescriptions drugs'' and stated ''that his fill-in pharmacists were previous drug abusers he had hired from a West Virginia Pharmacy Board facilitated drug rehabilitation program.'' *Id.* Chapman also ''denied knowing

[4] According to the MOA, in the spring of 2009, Chapman injured his back and was prescribed oxycodone and hydrocodone. GX 3, Appendix 3, at 1–2. As his pain increased, Chapman began using more drugs than were prescribed and stole several hundred tablets from his employer. *Id.* at 1. Chapman, however, reported his drug problem to his employer and entered into a recovery contract with the West Virginia Pharmacy Recover Network (PRN), which required that he attend Narcotics Anonymous/Alcoholics anonymous meetings, provide random drug screens, and see an addiction psychiatrist. *Id.* at 2. At the time he entered into the MOA, he had successfully completed the PRN's requirements and was ''under contract for an additional three year period.'' *Id.*

anything further about the nature of the [p]harmacy losses of'' controlled substances. *Id.*

During the June 30 interview, Chapman also admitted that he ''us[ed] marijuana illegally.'' *Id.* at 4. He told the DI that ''he uses an electronic cigarette or vaporizer device as a delivery mechanism for his marijuana.'' *Id.*

On July 19, 2016, the DI and a TFO served a search warrant on the Cabell-Huntington Hospital for Chapman's records. *Id.* at 5. The records show that on June 17, 2015,[5] as well as April 6 and July 18, 2016, ''Chapman was admitted . . . due to complications from an overdose.'' *Id.* at 5. Chapman underwent urine drug tests on each occasion, with the June 17, 2015 and April 6, 2016 test results showing that he was ''positive for opiates including oxycodone'' and the July 18 test results showing that he ''was positive for'' both cocaine and oxycodone. *Id.* The records for both the June 17, 2015 and April 6, 2016 admissions document that Chapman stated ''that he had taken Percocet prior to being admitted.'' *Id. See also* Appendix 6A, at 2 (April 6, 2016 discharge summary) (''discussed his urine tox screen with him and he states he took ½ percocet''); Appendix 6B, at 15 (June 17, 2015 discharge summary: ''The pt. denied taking anything other than Percocet several days prior to admission.'')

According to the DI, he queried the West Virginia Prescription Monitoring Program (PMP) to determine what prescriptions Chapman had been issued. GX 3, at 5. The query showed that ''Chapman had filled prescriptions for Tramadol and one prescription for hydrocodone in March 2016.'' *Id.* The query showed no prescriptions for other drugs. *Id.*

On July 21, 2016, the DI received another report from a pharmacy employee that Chapman had again taken oxycodone from the pharmacy. *Id.* at 4. The next day, the DI, along with a Task Force Officer and a Pharmacy Board Investigator again interviewed Chapman. *Id.* During the interview, ''Chapman admitted that he had been diverting . . . 200 to 300 milligrams every day [of] oxycodone or hydrocodone'' for his ''personal use'' and had done so ''for approximately [one] year.'' *Id.* Chapman admitted that he ''alter[ed] the [p]harmacy's computer and inventory records'' and that he ''shredd[ed] invoices from suppliers and destroy[ed] DEA 222 Forms and CSOS records.'' *Id.* He ''also admitted that he had been using cocaine during the past two years,'' as well as that ''his addiction was so strong that he couldn't wait for [the] MOA . . . to expire so that he could begin using his . . . [r]egistration to fuel his . . . addiction.'' *Id.*

On July 23, 2016, the DI received another report from the employee that Chapman had taken drugs from the pharmacy, in particular, a 100-count bottle of oxycodone. *Id.* at 4. On August 3, 2016, the DI received still another report from the employee that Chapman had taken narcotics from the pharmacy. *Id.* at 5.

The DI also attempted to conduct an audit of the pharmacy. *Id.* While the DI subpoenaed the records from the pharmacy's suppliers and was able to determine the total amount of drugs that the pharmacy had obtained, according to the DI, ''the [p]harmacy's internal records were so unreliable as to make an accurate count impossible.'' *Id.* Based on the records he obtained from just one supplier, the DI found that Respondent could not account for 20,000 pills of oxycodone 30 mg and hydrocodone 10 mg. *Id.* The DI noted that Chapman had also admitted to diverting oxycodone 15 mg. *Id.*

The DI also obtained a search warrant for the pharmacy's video surveillance records; these videos were submitted as part of the record. *Id.* According to the DI, these videos show ''Chapman entering the pharmacy and removing pills on two separate occasions,'' including one during which Chapman ''plac[ed] an unknown number of loose pills into his pocket,'' and another, during which Chapman removed a pill bottle from a locked storage cabinet. *Id.* at 5–6. In addition, the DI obtained photographs showing the various areas of the pharmacy and the location of the locked cabinet.[6] *Id.* at 6. One of the videos does show a person opening a locked cabinet at the pharmacy counter, removing a plastic bottle from the cabinet, and leaving the pharmacy.

Finally, the DI stated that ''[i]f Chapman had been candid about his role in the diversion of controlled substances during the June 30 AIW, I and my DEA colleagues would have pursued immediate criminal action against Chapman. We would also have been able to take additional steps—including seeking immediate administrative sanctions—to prevent additional diversion of controlled substances from the [p]harmacy.'' *Id.*

Discussion

Mootness

As found above, the registration at issue in this proceeding expired on August 31, 2017. According to the registration records of the Agency, Chapman has not filed either a renewal application or a new application for the pharmacy. Accordingly, there is neither a registration to revoke nor an application to act upon.

While ordinarily these facts would render this proceeding moot, *see Ronald J. Riegel,* 63 FR 67132, 67133 (1998), simultaneously with the issuance of the Show Cause Order, the former Acting Administrator ordered that Registrant's registration be immediately suspended. Pursuant to the authority granted by 21 U.S.C. 824(f), the former Acting Administrator authorized the seizure or placement under seal of the controlled substances possessed by Registrant pursuant to its registration. As found above, the Government seized various controlled substances pursuant to the Immediate Suspension Order. GX 3, at 2.

Under section 824(f), ''[u]pon a revocation order becoming final, all such controlled substances'' which have been seized or placed under seal ''shall be forfeited to the United States'' and ''[a]ll right, title, and interest in such controlled substances shall vest in the United States upon a revocation order becoming final.'' 21 U.S.C. 824(f). DEA has previously held that a registrant, who has been issued an immediate suspension order, cannot defeat the effect of this provision by allowing its registration to expire. *See Meetinghouse Community Pharmacy, Inc.,* 74 FR 10073, 10074 n.5 (2009); *RX Direct Pharmacy, Inc.,* 72 FR 54070, 54072 n.4 (2007). Thus, this proceeding presents the collateral consequence of who has title to the controlled substances that were seized. Accordingly, I hold that this case is not moot and proceed to the merits.

The Merits

Under the CSA, ''[a] registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). In the case of a retail

[5] While in his declaration, the DI stated that Chapman was admitted to the hospital on June 17, 2016, the records clearly show that this occurred on June 17, 2015. Appendix 6B.

[6] The DI also obtained a copy of court records showing that on September 8, 2016, Chapman entered into a guilty plea to a state court information which charged him with the felony offense of ''Obtaining Possession of a Controlled Substance by Fraud.'' GX 3, at 6.

pharmacy, which is deemed to be a practitioner, *see* id. § 802(21), Congress directed the Attorney General to consider the following factors in making the public interest determination:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Id.

''[T]hese factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). It is well settled that I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[ ] appropriate in determining whether'' to suspend or revoke an existing registration. *Id.; see also MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482.[7]

Also, pursuant to section 824(d), ''[t]he Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety.'' 21 U.S.C. 824(d)(1). Congress has defined ''the phrase 'imminent danger to the public health or safety' [to] mean[ ] that, due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under [the CSA], there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration.'' *Id.* § (d)(2).

Under the Agency's regulation, ''[a]t any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to . . . 21 U.S.C. 824(a) . . . are satisfied.'' 21 CFR 1301.44(e). In this matter, I have considered all of the factors and find that the Government's evidence with respect to factors four and five,[8] establishes that Registrant, through its owner, has committed acts which render its registration ''inconsistent with the public interest'' and which support the suspension of its registration. 21 U.S.C. 824(a)(4). I further find that the Government's evidence establishes that Registrant's misconduct satisfies the imminent danger standard of 21 U.S.C. 824(d), in that, Registrant's failure ''to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under'' the CSA created ''a substantial likelihood of an immediate threat that . . . abuse of a controlled substance will occur in the absence of an immediate suspension of [its] registration.''

Factor Four—Compliance With Applicable Laws Related to Controlled Substances

As found above, the evidence shows that Chapman, Registrant's PIC, was diverting narcotic controlled substances from the pharmacy's stock for his own misuse. This evidence includes: (1) The videos showing him unlocking the cabinet in which controlled substances were stored, removing a bottle of medication, and leaving the pharmacy; (2) the statements of a pharmacy employee to the DI as to various instances in which oxycodone went missing, including the July 18, 2016 incident, when he passed out at his desk and was hospitalized; (3) the UDS results for the various hospitalizations including the July 18, 2016 positive result for oxycodone (which was also positive for cocaine); (4) his subsequent admission to Investigators during the July 21, 2016 interview that he had been diverting 200 to 300 milligrams every day of oxycodone or hydrocodone for approximately one year; (5) the DI's finding that at least 20,000 dosage units of oxycodone 30 mg and hydrocodone 10 mg could not be accounted for; and (6) the DI's statement that his query of the state PMP showed that Chapman had filled only prescriptions for tramadol and one hydrocodone prescription in March 2016.

Under the Controlled Substances Act, it is ''unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this subchapter.'' 21 U.S.C. 844(a). While Chapman, as the PIC of a registered pharmacy, was authorized to order controlled substances for the pharmacy and to possess controlled substances in his capacity as the Registrant's PIC, he was generally authorized to do so only for the purpose of dispensing the controlled substances to patients ''pursuant to the lawful order of a practitioner,'' *i.e.,* a prescription.[9] *See* 21 U.S.C. 822(b) (''Persons registered by the Attorney General under this subchapter to . . . dispense controlled substances . . . are *authorized to possess . . . distribute, or dispense such substance . . . to the extent authorized by their registration and in conformity with the other provision of this subchapter.*'') (emphasis added); *id.* § 823(f) (''The Attorney general shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense . . . .''). *id.* § 802 (''The term 'dispense' means to deliver a controlled

[7] In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's or applicant's misconduct. *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

[8] The Government submitted no evidence as to Factor One. As to Factor Three, the Government submitted evidence that after issuance of the Show Cause Order, Chapman pled guilty in state court to Obtaining Possession of a Controlled Substance by Fraud. While the evidence also includes a Post-Conviction Procedural Order but not a Judgment, the Government did not allege Chapman's conviction for this offense as grounds for the proceeding. However, even if a Judgment has been issued, the Government did not provide him with notice that it intended to rely on either Factor Three or 21 U.S.C. 824(a)(2). Thus, I consider Chapman's guilty plea only as additional evidence to support the allegations (not that such evidence is needed).

In its Request for Final Agency Action, the Government did not address the applicability of Factor Two (the Registrant's experience in dispensing controlled substances) to the various acts of misconduct that were alleged and proved. As explained in this Decision, the record establishes that Registrant engaged in the unlawful distribution of controlled substances and committed various recordkeeping violations. These acts of misconduct are relevant in assessing both Registrant's compliance with applicable laws related to controlled substances as well as its experience in dispensing controlled substances.

[9] Under a DEA regulation, a pharmacy is also allowed to distribute a small quantity of controlled substances to another practitioner ''without being registered to distribute,'' provided that ''[t]he practitioner to whom the controlled substance is to be distributed is registered under the Act to dispense that controlled substance.'' 21 CFR 1307.11(a). Those distributions cannot, however, exceed, on a ''calendar year'' basis, ''5 percent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the same calendar year.'' *Id.* Chapman's distribution of controlled substances to himself does not come within this exemption.

substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner''); *see also* 21 CFR 1300.01(a) (''*Prescription* means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user . . . .''). As Registrant's PIC, Chapman was not authorized to then distribute the controlled substances to himself. Moreover, because under West Virginia law, a limited liability company has legal personality (*see* West Va. § 841(a)(1)) and Chip RX, L.L.C., held the registration, it unlawfully distributed controlled substances to Chapman in violation of 21 U.S.C. 841(a)(1) (''Except as authorized by this subchapter, it shall be unlawful for any person knowing or intentionally . . . to distribute . . . a controlled substance.'').

The evidence also shows that Registrant (and Chapman) violated the CSA by failing maintain ''a complete and accurate'' record of each such [controlled] substance . . . received, sold, delivered or otherwise disposed of . . . .'' 21 U.S.C. § 827(a)(3). Specifically, Chapman admitted that he shredded invoices from suppliers. *See id., see also* 21 CFR 1304.04(a) (requiring that records be kept ''for at least 2 years from the date of such inventory or records''); *id.* § 1304.22(c) (incorporating 21 CFR 1304.22(a)(2)(i), (ii), (iv), (vii), (ix)). Indeed, Registrant was required to maintain records of its distribution to Chapman.

Moreover, Chapman admitted that he destroyed both schedule II order forms and CSOS (Controlled Substance Ordering System) electronic records. Chapman's admission establishes that Registrant violated 21 U.S.C. 828(c)(2), which requires that a purchaser of a schedule II controlled substance retain a duplicate copy of a DEA Order Form ''if such order is accepted'' by a supplier and ''preserve such duplicate for a period of two years and make it available for inspection or copying.'' Chapman's admission also establishes that Registrant violated section 828(c)(2) by failing to maintain CSOS records. *See also* 21 CFR 1305.27(a) (''A purchaser must, for each order filled, retain the original signed order and all linked records for that order for two years.'').

Thus, the evidence with respect to Registrant's compliance with applicable laws related to controlled substances establishes that Registrant committed numerous violations of the CSA by unlawfully distributing controlled substances to Chapman in violation of 21 U.S.C. 841(a)(1); it also shows that Registrant and Chapman violated the recordkeeping provisions of 21 U.S.C. 827(a)(3), as well as provisions requiring the maintenance of schedule II order forms. 21 U.S.C. 828(a)(2). Finally, the evidence also shows that Registrant's principal and PIC violated 21 U.S.C. 844(a) by obtaining controlled substances other than by means ''pursuant to a valid prescription . . . from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by'' the CSA.

Factor Five—Such Other Conduct Which May Threaten Public Health and Safety

The Agency has also long held that self-abuse of a controlled substance constitutes such other conduct which may threaten public health and safety. *See Tyson D. Quy,* 78 FR 47412 (2013); *Tony T. Bui,* 75 FR 49979 (2010); *Kenneth Wayne Green, Jr.,* 59 FR 51453 (1994); *David E. Trawick,* 53 FR 5,326 (1988). While Registrant is not an individual but rather a limited liability company, the Agency has long held that the misconduct of an entity's principal is properly considered in determining whether to revoke the entity's registration. *See G & O Pharmacy of Paducah,* 68 FR 43752, 43753 (2003). That Chapman's personal abuse of controlled substances, which includes his abuse of cocaine, narcotics, and marijuana on the job, may have threatened public health and safety is indisputable given the evidence that he incorrectly filled a prescription and pharmacy staff had to correct his error.[10]

The Government also alleged that Chapman made several materially false statements to agency Investigators. As recognized by the Sixth Circuit,''[c]andor during DEA investigations, regardless of the severity of the violations alleged, is considered by the DEA to be an important factor when assessing whether a [practitioner's] registration is consistent with the public interest.'' *Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005). To be actionable, the Government is required to show that the statement was false and material to the investigation. *See Roy S. Schwartz,* 79 FR 34360, 34363 n.6 (2014); *Belinda R. Mori,* 78 FR 36582, 36589 (2013).

As the Supreme Court has explained, a false statement is material if it '' 'has a natural tendency to influence, or was capable of influencing the decision of the decisionmaking body to which it was addressed.' '' *Kungys* v. *United States,* 485 U.S. 755, 770 (1988) (quoting *Weinstock* v. *United States,* 231 F.2d 699, 701 (D.C. Cir. 1956)). The Court has further explained that:

> it has never been the test of materiality that the misrepresentation . . . would more likely than not have produced an erroneous decision, or even that it would more likely than not have triggered an investigation. Rather, the test is whether the misrepresentation . . . was predictably capable of affecting, *i.e.,* had a natural tendency to affect, the official decision.

485 U.S. at 770–71. ''It makes no difference that a specific falsification did not exert influence so long as it had the capacity to do so.'' *United States* v. *Alemany Rivera,* 781 F.2d 229, 234 (1st Cir. 1985).

The evidence establishes that Chapman made several materially false statements to the Investigators. First, Chapman told the Investigators during the June 30, 2016 interview that ''10 to 15 oxycodone or hydrocodone pills would be missing from the [p]harmacy . . . perhaps 15–20 times in the prior year'' and that Registrant had ''a total loss of perhaps 300 oxycodone and hydrocodone pills.'' Second, during the June 30, 2016 interview, Chapman ''denied that he was abusing prescription drugs'' and attributed the diversion to fill-in pharmacists he employed who were previous drug abusers and were hired through a State Board rehabilitation program. He also ''denied knowing anything further about the nature of the [p]harmacy's losses'' of controlled substances.

Chapman's statements regarding the scope of the diversion of drugs from Registrant were false because the diversion was far more extensive than what he claimed during the June 30 interview, as he ultimately admitted during the July 22, 2016 interview, when he acknowledged diverting 200 to 300 milligrams per day of oxycodone or hydrocodone for personal use. So too, his statements during the June 30 interview in which he denied that he was abusing drugs, as well as that he knew anything further about the nature of the pharmacy's losses, were also false as he ultimately admitted during the July 22 interview that he was abusing narcotic prescription drugs and was diverting large quantities on a daily basis.

I further conclude that these statements were capable of influencing the decisionmaking process of the Agency because Chapman attempted to minimize the scope of the criminal conduct that was occurring at

[10] Factor Five does not require that the Government prove an actual threat to public health or safety and thus, the Government is not required to identify any specific instance in which a practitioner's (or its employee's) self-abuse created an actual threat to the health and safety of its patients.

Registrant, both with respect to the volume of drugs being diverted and by denying that he was engaged in diverting and abusing the controlled substances. As explained above, Registrant's and Chapman's misconduct in diverting drugs, which the latter personally abused, was actionable misconduct under both Factor Four (compliance with applicable laws related to controlled substances) and Factor Five (other conduct which may threaten public health and safety). As the DI explained, had Chapman been candid during the June 30, 2016 interview, he and his colleagues ''would have pursued immediate criminal action against Chapman'' as well as administrative action against Registrant. Indeed, Chapman's subsequent admissions during the July 22, 2016 interview supported both criminal charges against Chapman and the Immediate Suspension Order.

Accordingly, I conclude that the evidence with respect to Factor Five establishes that Registrant's principal was abusing controlled substances and that he made several materially false statements to DEA investigators. I also conclude that these acts constitute actionable misconduct which may threaten public health and safety.

Summary of Factors Four and Five and Imminent Danger

As found above, the Government's evidence establishes that Registrant unlawfully distributed controlled substances to Chapman and failed to maintain required records. The evidence also establishes that Registrant's principal and pharmacist in charge unlawfully possessed controlled substances, destroyed records that Registrant was required to maintain, abused controlled substances and made materially false statements to DEA Investigators. I therefore find that Registrant has committed such acts as to render its registration inconsistent with the public interest. 21 U.S.C. 824(a)(4).

For purposes of the imminent danger inquiry, these findings also support the conclusion that Registrant has ''fail[ed] . . . to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under'' the CSA. 21 U.S.C. 824(d)(2). Also, the evidence that Chapman was diverting 200 to 300 milligrams of narcotics per day, which he then abused (along with the evidence showing that he was hospitalized for an overdose on multiple occasions), establishes that there was ''a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance [would] occur in the absence of the immediate suspension of [Registrant'] registration.'' *Id.* I therefor affirm the issuance of the Immediate Suspension Order.

Pursuant to 21 U.S.C. 824(f), ''[u]pon a revocation order becoming final, all . . . controlled substances'' seized pursuant to a suspension order ''shall be forfeited to the United States'' and ''[a]ll right, title, and interest in such controlled substances shall vest in the United States upon a revocation order becoming final.'' As the Agency has previously held, a registrant cannot defeat the effect of this provision by allowing its registration to expire.'' *S & S Pharmacy, Inc., d/b/a Platinum Pharmacy & Compounding,* 78 FR 57656, 57659 (2013) (citing *Meetinghouse Community Pharmacy, Inc.,* 74 FR 10073, 10074 n.5 (2009); *RX Direct Pharmacy, Inc.,* 72 FR 54070, 54072 n.4 (2007)). Registrant had the right to challenge the Immediate Suspension Order before the Agency but chose not to. And had Registrant not allowed its registration to expire, I would have revoked it.

Accordingly, I will order that the controlled substances seized pursuant to the Immediate Suspension Order be forfeited to the United States. 21 U.S.C. 824(f). I will also declare that ''[a]ll, right, title, and interest in'' the controlled substances that were seized pursuant to the Suspension Order have vested in the United States. *Id.*

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a) and (d), as well as 28 CFR 0.100(b), I order that the Order of Immediate Suspension issued to Chip RX d/b/a City Center Pharmacy be, and it hereby is, affirmed. Pursuant to the authority vested in me by 21 U.S.C. 824(f), I order that all controlled substances seized pursuant to the Order of Immediate Suspension be, and they hereby are, forfeited to the United States. Pursuant to the authority vested in me by 21 U.S.C. 824(f), I also declare that all right, title, and interest in all controlled substances seized pursuant to the Order of Immediate Suspension be, and they hereby are, vested in the United States. This Order is applicable December 6, 2017.

Dated: October 31, 2017.

Robert W. Patterson,

Acting Administrator.

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BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Cerilliant Corporation

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before January 5, 2018.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on May 23, 2017, Cerilliant Corporation, 811 Paloma Drive, Suite A, Round Rock, Texas 78665–2402 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
ADB-FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-)4-fluorobenzyl)-1-H-indazole-3-carboxamide)	7010	I
MDMB-FUBINACA (Methyl-2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	7020	I
MAB-CHMINACA (N-(1-amino-3,3dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	7032	I