

Directorate for the quality of Medicines (EDQM). In order to ensure that its product will meet European specifications, the company seeks to import morphine supplied by EDQM for use as reference standards.

Dated: December 2, 2019.

William T. McDermott, Assistant Administrator.

[FR Doc. 2019-27093 Filed 12-13-19; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-560]

Importer of Controlled Substances Application: Novitium Pharma LLC

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 15, 2020. Such persons may also file a written request for a hearing on the application on or before January 15, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION:

In accordance with 21 CFR 1301.34(a), this is notice that on July 18, 2018, Novitium Pharma, LLC., 70 Lake Drive, East Windsor, New Jersey 08520 applied to be registered as an importer of the following basic class of controlled substance:

Table with 3 columns: Controlled substance, Drug code, Schedule. Row 1: Levorphanol, 9220, II

The company plans to import the controlled substance to develop the manufacturing process for a drug product that will in turn be used to

produce a tablet equivalent to the current brand product.

Dated: December 3, 2019.

William T. McDermott, Assistant Administrator.

[FR Doc. 2019-27095 Filed 12-13-19; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-553]

Importer of Controlled Substances Application: Mylan Pharmaceuticals Inc.

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 15, 2020. Such persons may also file a written request for a hearing on the application on or before January 15, 2020

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION:

In accordance with 21 CFR 1301.34(a), this is notice that on October 17, 2019, Mylan Pharmaceuticals Inc., 3711 Collins Ferry Road, Morgantown, West Virginia 26505 applied to be registered as an importer of the following basic classes of controlled substances:

Table with 3 columns: Controlled substance, Drug code, Schedule. Rows: Amphetamine (1100, II), Methyphenidate (1724, II), Oxycodone (9143, II), Hydromorphone (9150, II), Methadone (9250, II), Morphine (9300, II), Fentanyl (9801, II)

The company plans to import the listed controlled substances in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company's own domestically-manufactured FDF. This analysis is required to allow the company to export domestically-manufactured FDF to foreign markets.

Authorization will not extend to the import of Food and Drug Administration approved or non-approved finished dosage forms for commercial sale.

Dated: November 14, 2019.

William T. McDermott, Assistant Administrator.

[FR Doc. 2019-27094 Filed 12-13-19; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Jeffrey D. Olsen, M.D.; Decision and Order

On August 2, 2016, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (OSC) and Immediate Suspension of Registration (ISO) to Jeffrey D. Olsen, M.D. (hereinafter, Registrant), of Newport Beach, CA. Order to Show Cause and Immediate Suspension of Registration (hereinafter collectively, OSC 2), at 1; see also Government Exhibit (hereinafter, GX) 26, at 1-6. OSC 2 informed Registrant of the immediate suspension of his DEA Certificate of Registration (hereinafter, COR) FO6043638 pursuant to 21 U.S.C. 824(d) "because . . . [his] continued registration constitute[d] an imminent danger to the public health and safety." Id.

The substantive ground for the proceeding, as alleged in OSC 2, was that Registrant's "continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f)." Id. (citing 21 U.S.C. 824(a)(4)). Specifically, the OSC alleged that Registrant issued numerous prescriptions outside the usual course of the professional practice of medicine in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1306.04(a) and in violation of California law and the minimum standards of medical practice in California. Id. at 2-4. The OSC stated that "[Registrant's] conduct, viewed as a whole, 'completely betrayed any semblance of legitimate medical treatment.'" Id. at 4 (citing Jack A. Danton, D.O., 76 FR 60900, 60904

(2011)). Further, OSC 2 alleged that, on March 15, 2016, DEA had served Registrant with an initial Order to Show Cause and Immediate Suspension Order (hereinafter, collectively OSC 1), which immediately suspended Registrant's previous COR B02524204. *Id.* at 1–2; *see also* GX 26, at 7–12 (OSC 1). After receiving OSC 1, Registrant surrendered his DEA COR B02524204 for cause on March 18, 2016. GX 17 (Voluntary Surrender of Controlled Substances Privileges). However, OSC 2 alleged that on May 20, 2016, Registrant filed an application for a new COR, and he materially falsified his application by providing an answer in the negative to the question of whether he had ever surrendered his federal COR. OSC 2, at 2. OSC 2 further alleged that pursuant to 21 U.S.C. 824, this action “constitute[d] independent grounds for revocation.” *Id.* OSC 2 also enclosed a copy of, and incorporated by reference, OSC 1, which detailed numerous other issuances of prescriptions outside the usual course of the professional practice of medicine in violation of 21 U.S.C. 841(a)(1) and 21 CFR § 1306.04(a) and in violation of California law and the minimum standards of medical practice in California. OSC 2, at 2; *see also* GX 26, at 7–12 (OSC 1).

OSC 2 notified Registrant of his right to request a hearing on the allegations, or to submit a written statement while waiving his right to a hearing, the procedures for electing either option, and the consequence of failing to elect either option. OSC 2, at 5–6 (citing 21 CFR 1301.43).

#### Adequacy of Service and Timeliness of Hearing Request

In a Declaration dated December 22, 2017, a Diversion Investigator (hereinafter, DI) assigned to the Los Angeles Field Division declared under penalty of perjury that, in the presence of a DEA Special Agent and a DEA Task Force Officer, she personally served OSC 2 on Registrant at his registered address on August 3, 2016. GX 31, at 7 (Second Sworn DI Declaration, dated Dec. 22, 2017). According to the DI, Registrant acknowledged receipt of OSC 2 by signing a DEA–12, Receipt for Cash or Other Items, on August 3, 2016. GX 27 (DEA–12 signed by Registrant).

Based on the DI's Declaration, the Government's written representations, and my review of the record, I find that the Government accomplished service of OSC 2 on Registrant on August 3, 2016.

On October 18, 2016, the Office of Administrative Law Judges (hereinafter, OALJ) received “what appeared to be a hearing request and a request for an

extension of time to respond to the OSC.” RFAA, at 2; *see also* GX 29 (Registrant's Request for Reasonable Time Extension). The request was signed by Registrant, referenced an attorney, and requested additional time “due to recent medical problems, deterioration of his health and due to the time consuming, expensive, medical care required on his behalf.” GX 29, at 1 (capitalization omitted). The request described multiple medical complaints and stated, “This long list of simultaneous, major medical problems have converged upon and legitimately burdened [Registrant], who has struggled with the symptoms, signs and consequences of all of these.” *Id.* at 1.

The matter was assigned to the Chief Administrative Law Judge (hereinafter, ALJ), who denied Registrant's request for an extension of time, found that Registrant waived his opportunity for a hearing, and terminated the proceeding. GX 30 (Order Denying the Registrant's Request for Additional Time to Respond to the Order to Show Cause/Immediate Suspension of Registration and Terminating Proceedings, dated October 28, 2016), at 4. The Chief ALJ found that the Registrant's letter “arrived 76 days after service—46 days after the deadline to respond to the OSC/ISO.” *Id.* at 1. The Chief ALJ cited 21 CFR 1301.43(d), which states in relevant part that a registrant who fails to request a timely hearing, “shall be deemed to have waived the opportunity for a hearing or to participate in the hearing, unless such person shows good cause for such failure.” *See* GX 30, at 2.

I concur with the Chief ALJ that, in this case, “[i]t is not necessary to accept the Government's broad and uncompromising suggestion that preoccupation with other matters cannot constitute good cause for an untimely filing, under any circumstances, to decide the [Registrant's] Enlargement Motion.” *Id.* at 3.

I further agree with the Chief ALJ's reasoning in denying Registrant's request for an extension of time:

Even accepting, *arguendo*, that . . . [Registrant's] medical conditions are serious and impactful, as described, they do not present a scenario where the [Registrant] was precluded from answering for 76 days. While certainly true that responding and seeking out counsel would have required some commitment of time, sending a response to the OCS/ISO was hardly rendered ‘impossible,’ by his ailments as he described them and by his other distractions. The [Registrant] does not allege that he was hospitalized or otherwise unable (physically or mentally) to prepare and submit a response or seek out representation.

*Id.*

I therefore find that, because Registrant did not provide good cause for his failure to meet the deadline for requesting a hearing, he waived his right to a hearing.

On January 2, 2018, the Government forwarded its Request for Final Agency Action (RFAA), along with the evidentiary record in this matter, to my office. The Government argued that Registrant offered no evidence that he accepted responsibility for [his] actions and would not engage in future misconduct, and his COR should be revoked, because it is contrary to the public interest. RFAA, at 21. I issue this Decision and Order after considering the entire record before me. 21 CFR 1301.43(e).

#### Question of Mootness

On January 7, 2019, I issued an Order taking notice of the Agency's registration records, which showed that on December 31, 2018, Registrant's COR was due to expire, and requested that the parties address whether the case was moot. January Order, at 1.

On January 15, 2019, the Government timely responded to my Order with a two-page filing arguing that “[w]here, as here, the DEA registrations that are the subject of a pending litigation expire or otherwise terminate prior to the issuance of a final order, DEA precedent (with one recent exception) makes clear that the matter should be dismissed as moot, at least absent collateral consequences not present here.” Government's Response to Order and Suggestion of Mootness (hereinafter, GR), at 1 (citations omitted). The Government requested, “consistent with the significant majority of agency precedent on point” that this case be dismissed as moot “notwithstanding” a DEA decision to the contrary. *Id.* at 2. Beyond citation of the cases, the Government did not elaborate on, or offer the legal analysis behind, its assertions regarding “controlling agency precedent” and the “significant majority of agency precedent on point.” *Id.* at 1, 2.

Registrant did not submit a filing or otherwise respond to my Order.<sup>1</sup>

My analysis of the constitutional origins of administrative agencies and of federal and Agency decisions addressing mootness sets me on a

<sup>1</sup> As a courtesy, my office gave Registrant an opportunity to respond to my Order. Although my office mailed the Order to the most recent address he provided in these proceedings, the address on Registrant's Request, the certified envelope was returned “unclaimed.” When my office re-mailed the Order by first-class mail, it was not returned as undeliverable. Thus, it appears that Registrant received a copy of my Order.

different course from many, but not all, previous Agency decisions in which the registrant allowed the registration at issue in an Immediate Suspension Order and/or in an Order to Show Cause (hereinafter, ISO/OSC) to expire before final adjudication of that ISO/OSC.<sup>2</sup> As an initial matter, therefore, I note that Agency decisions from 1977 to the present do not exhibit uniformity regarding mootness or the ramifications of a registration's expiration before issuance of a final decision. Instead, almost since the Agency's inception, my predecessors have grappled with this matter.<sup>3</sup>

*Park and King Pharmacy*, 52 FR 13136 (1987), involved an OSC alleging that the registrant dispensed controlled substances other than pursuant to the lawful order of a practitioner, and that the president and registered pharmacist

<sup>2</sup> In *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502 (2009), the Supreme Court acknowledged that administrative agency adjudications change course and addressed how an agency may do so and continue to pass muster on appellate review under the Administrative Procedure Act (hereinafter, APA). First, the Supreme Court pointed out that the APA does not mention a heightened standard of review for agency adjudication course adjustments. *Id.* at 514. Instead, it stated that the narrow and deferential standard of review of agency adjudications set out in 5 U.S.C. 706 continues to apply. *Id.* at 513–14 (concluding that “our opinion in *State Farm* neither held nor implied that every agency action representing a policy change must be justified by reasons more substantial than those required to adopt a policy in the first instance.”).

Second, according to the Supreme Court, an agency would “ordinarily display awareness that it is changing position” and it may not “depart from a prior policy *sub silentio* or simply disregard rules that are still on the books.” *Id.* at 515. Further, an agency must “show that there are good reasons for the new policy” but need not “demonstrate to a court’s satisfaction that the reasons for the new policy are *better* than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better.” *Id.* (emphases in original). Finally, the Supreme Court had warned in an earlier decision that an “irrational departure” from agency policy, “as opposed to an avowed alteration of it,” could be overturned as arbitrary and capricious, or an abuse of discretion. *I.N.S. v. Yueh-Shaio Yang*, 519 U.S. 26, 32 (1996).

Given the lack of uniformity over time in the body of Agency decisions concerning adjudications when the registration at issue is allowed to expire before issuance of a final decision, my current mootness-related analysis may not be the “agency change” the Supreme Court contemplated in *Fox Television*. Nevertheless, I am following the parameters the Court announced to support my CSA-related responsibilities and out of respect for, and to facilitate, any appellate review.

<sup>3</sup> Mootness, as described in federal case law, differs from the mootness that results from action such as an appellate court’s reversal of the criminal convictions on which an OSC charge under 21 U.S.C. 824(a)(2) is based. *See, e.g., William Russell Greenfield, Jr., M.D.*, 42 FR 34386, 34386 (1977) (finding no lawful basis for revocation after the underlying criminal convictions were overturned). I agree with the mootness finding in *William Russell Greenfield, Jr., M.D.*, because the criminal convictions, which were the factual premise and essential bases of the OSC, were overturned.

of registrant pled nolo contendere to the felony possession of a controlled substance with intent to deliver or sell. 52 FR at 13136. *Park and King Pharmacy* is among the earliest decisions addressing the expiration of a registration before issuance of a final decision. In it, my predecessor rejected the suggestion that the matter was moot, adjudicated the matter, and revoked the registration. *Id.* at 13,137. According to the decision, both DEA and its predecessor agency, since implementation of the Controlled Substances Act (hereinafter, CSA), “maintain[ed] registrations on a day-to-day basis pending resolution of administrative proceedings seeking to revoke such registrations.” *Id.* Also according to the decision, this “administrative ‘hold’” prevented both the registration from expiring and Respondent from renewing the registration. *Id.* at 13,138. Based on this understanding, my predecessor concluded that, “[N]either the nominal expiration date on the face of Respondent’s registration nor . . . [Respondent’s] inability to file a renewal application have any effect upon the matter pending before the Administrator.”<sup>4</sup> *Id.*

*Park and King Pharmacy* was reconsidered in late 1998. In *Ronald J. Riegel, D.V.M.*, 63 FR 67132 (1998), the then-Acting Deputy Administrator stated that he was “troubled” by *Park and King Pharmacy*, because “no authority was cited . . . for the position that an expired registration can still be revoked if no renewal application has been filed.”<sup>5</sup> *Id.* at 67,133. He agreed

<sup>4</sup> The decision notes four points that DEA counsel made in support of adjudication to a final decision and revocation. First, DEA counsel argued that, had respondent been a medical practitioner, “there is no question but that the DEA would not permit him to surrender his registration . . . during the 23rd hour of a proceeding.” 52 FR at 13137. Second, Respondent’s ability to “direct the destiny of his registration” terminated with the issuance of the OSC. *Id.* Third, permitting an individual or entity under an OSC to “duck the issue” at the “last minute” would enable him/it to “put the agency to the expense of a hearing, with a commitment of public resources which is not insubstantial.” *Id.* The individual/entity could thereby “avoid any or all of the collateral sanctions which accompany the revocation of a registration[,] . . . reopen at a later time or in a different location, submitting a new application for registration and truthfully answering on such application that he had never had a registration revoked . . . . This would diminish the chances that the application would be noticed for further administrative proceedings.” *Id.* Fourth, if Respondent’s “last minute withdrawal” meant that no final order would issue, “another full hearing on the new application might be required . . . prevent[ing] the administrative processes of DEA from operating effectively.” *Id.*

<sup>5</sup> In *Ronald J. Riegel, D.V.M.*, the OSC was based on 21 U.S.C. 824(a)(2) (controlled substance-related felony conviction) and (a)(4) (contrary to the public interest). The veterinarian’s registration expired

with DEA counsel who argued that “there is no viable registration to revoke.” *Id.* The then-Acting Deputy Administrator determined, however, that “it would be unfair to now terminate the proceedings without resolution . . . ‘mid-case, without notice [to Respondent] and opportunity to comply with the changed procedure.’” *Id.* He revoked the veterinarian’s registration after stating that he was “deeply troubled by Respondent’s conduct.” *Id.* at 67,134. Agency decisions from then until the end of 2006 concerning similar facts cited mootness and dismissed the OSCs when the registration at issue had been allowed to expire during OSC proceedings.<sup>6</sup>

At the end of 2006, the then-Deputy Administrator (later, Administrator) repudiated *Ronald J. Riegel, D.V.M.* and suggested multiple reasons, legal and practical, for not finding mootness. *William R. Lockridge, M.D.*, 71 FR 77,791 (2006). In that case, the ISO/OSC charged respondent with issuing prescriptions for persons he never physically examined and, thus, without a legitimate medical purpose. Many of the reasons cited in *William R. Lockridge, M.D.* had been discussed in *Park and King Pharmacy* as arguments raised by DEA counsel.

First, *William R. Lockridge, M.D.* stated that Article III’s “case or controversy” limitation does not apply to federal administrative agency adjudications.

Having carefully considered . . . [*Ronald J. Riegel, D.V.M.*], as well as authorities discussing the mootness doctrine in both the judicial and administrative settings, I conclude that Riegel is not controlling. “[A]n administrative agency is not bound by the constitutional requirement of a ‘case or controversy’ that limits the authority of [A]rticle III courts to rule on moot issues.” *Id.* at 77796.

Second, *William R. Lockridge, M.D.* stated that its repudiation of mootness “finds ample support” in “long settled principles . . . applied by the courts.” *Id.* at 77797. Citing the Supreme Court, *William R. Lockridge, M.D.* stated, “[A]

about three months after the OSC was issued and the doctor did not submit a renewal application. 63 FR at 67132.

<sup>6</sup> *Daniel Koller, D.V.M.*, 71 FR 66975, 66981 (2006) (concluding that the revocation portion of the OSC was moot because the registration expired and “Respondent did not file a renewal application, let alone a timely one, for this registration”); *William Franklin Prior, Jr., M.D.*, 64 FR 15806, 15807 (1999) (citing mootness to terminate proceedings initiated pursuant to 21 U.S.C. 823(f), 824(a)(1) (materially falsified application), and 824(a)(4) (against the public interest) because Respondent’s criminal plea agreement required him to surrender his registration and withdraw his pending application).

defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice' because 'if it did, the courts would be compelled to leave "[t]he defendant . . . free to return to his old ways.'" *Id.* (citing *Friends of the Earth, Inc. v. Laidlaw Env. Servs., Inc.*, 528 U.S. 167, 189 (2000)). *William R. Lockridge, M.D.* pointed out that the standard for determining whether a defendant's voluntary conduct moots a case is stringent—"if subsequent events made it absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur." 71 FR at 77797 (citing *Friends of the Earth*, 528 U.S. at 189). Because Respondent had not submitted any "evidence (such as a declaration) establishing that he intends to permanently cease the practice of medicine. . . . Respondent can apply for a new registration at any time and could re-engage in the practice at issue here." 71 FR at 77797 (citing 21 CFR 1301.52(a)). *William R. Lockridge, M.D.* concluded that "[i]t is thus not "absolutely clear that [Respondent's] allegedly wrongful behavior could not reasonably be expected to recur.'" 71 FR at 77797 (citing *Friends of the Earth*, 528 U.S. at 189).

Third, *William R. Lockridge, M.D.* determined that the collateral consequences of an OSC militate against finding mootness. Citing "several courts . . . in cases involving sanctions against licensed professionals such as attorneys," *William R. Lockridge, M.D.* found that "even a temporary suspension followed by a reinstatement does not moot a challenge to the initial suspension because the action 'is harmful to a [professional's] reputation'" and this possibility is sufficient to preclude a finding of mootness. 71 FR at 77,797 (citing *In re Surrick*, 338 F.3d 224, 230 (3d Cir. 2003)). Likewise, according to *William R. Lockridge, M.D.*, the issuance of an ISO along with an OSC is an "extraordinary step to protect public health and safety" that has potentially harmed Respondent's reputation. 71 FR at 77 797. Finally, *William R. Lockridge, M.D.* noted that an additional collateral consequence to an ISO is being required to report the ISO when renewing a state medical license and when applying for a DEA registration. *Id.*

Fourth, *William R. Lockridge, M.D.* further noted that both parties had "expended substantial resources in litigating this case," and that the ALJ "committed an extensive amount of time to preparing her decision." *Id.* As such, it reasoned, "[t]o dismiss this proceeding without making the findings

which the evidence in this case compels would prejudice the public interest." *Id.* Thus, *William R. Lockridge, M.D.* concluded, "Respondent's failure to submit a renewal application does not preclude the entry of a final order in this matter." *Id.* Agency decisions into the middle of 2007 cited *William R. Lockridge, M.D.*<sup>8</sup>

Starting in the middle of 2007, adjudications during which registrations were allowed to expire before the issuance of a final decision were resolved in particularly fact-specific ways. *Ronald J. Riegel, D.V.M.* and its progeny, despite the more recent and substantive *William R. Lockridge, M.D.* decision, controlled adjudications and were cited to moot proceedings.<sup>9</sup> Further, the Administrator initiated dismissals due to mootness after taking official notice of the status of the registration at issue in DEA's database.<sup>10</sup>

<sup>7</sup> *William R. Lockridge, M.D.* affirmed the ISO and cancelled Respondent's DEA number. It did not dismiss the OSC.

<sup>8</sup> See *Trinity Health Care Corp., D/B/A Oviedo Discount Pharmacy*, 72 FR 30849, n.14 (2007) (concluding that the case is not moot, declining to adopt the ALJ's recommendation to revoke the registration, affirming the ISO, and stating that "there is neither an existing registration to revoke nor a pending application to deny"); *Rose Mary Jacinta Lewis, M.D.*, 72 FR 4035, 4042 (2007) (affirming the ISO, cancelling the registration number, but not dismissing the OSC).

<sup>9</sup> See *Amy S. Benjamin, N.P.*, 77 FR 72408, 72409 (2012) (citing *Ronald J. Riegel, D.V.M.* and dismissing the OSC as moot); *Louisiana All Snax, Inc.*, 76 FR 20034 (2011) (dismissing as moot an OSC alleging lack of state authority after the ALJ anticipated mootness based on the registration's expiration date and the 25-day mandated period for the filing of exceptions); *Thomas E. Mitchell, M.D.*, 76 FR 20032 (2011) (dismissing as moot an OSC alleging lack of state authority and specifically noting that Respondent must again be authorized to dispense controlled substances under the laws of the state in which he practices before he would be entitled to a registration); *John G. Costino, D.O.*, 76 FR 4940 (2011) (dismissing as moot an OSC alleging lack of state authority); *Kermit B. Gosnell, M.D.*, 76 FR 4938, 4938–39 (2011) (rejecting the ALJ's recommended decision, concluding the case is moot, and dismissing the OSC); *Sylvester A. Nathan*, 74 FR 17516 (2009) (dismissing as moot an OSC alleging lack of state authority); *William W. Nucklos, M.D.*, 73 FR 34330 (2008) (dismissing as moot the OSC based on ten felony convictions, and noting that dismissal on mootness grounds does not have collateral estoppel effect if Respondent were to apply for a registration in the future); *Benjamin Levine, M.D.*, 73 FR 34329 (2008) (dismissing as moot the OSC based on material falsification, loss of state authority, and acts inconsistent with the public interest, and noting that dismissal on mootness grounds does not have collateral estoppel effect if Respondent were to apply for a registration in the future); *David L. Wood, M.D.*, 72 FR 54936 (2007) (dismissing as moot the OSC after citing *Ronald J. Riegel, D.V.M.* and limiting *William R. Lockridge, M.D.*'s application to ISOs).

<sup>10</sup> See *Donald Kenneth Shreves, D.V.M.*, 83 FR 22518, 22518 (2018) (dismissing as moot "effective immediately" an OSC alleging lack of state authority after taking official notice of Registrant's registration record); *Keith F. Ostrosky, D.D.S.*, 83 FR 12406 (2018) (same); *Mohammed S. Aljanaby, M.D.*,

Meanwhile, *William R. Lockridge, M.D.* was explicitly limited to ISOs, but not uniformly applied to them.<sup>11</sup> Indeed, over time, the analysis actually applied to ISO cases that cited *William R. Lockridge, M.D.* was reduced to invoking *William R. Lockridge, M.D.* and describing it as a "limited exception to the mootness rule" due to the "collateral consequences" associated with an ISO.<sup>12</sup> The full scope of the "collateral consequences" addressed in *William R. Lockridge, M.D.*, in turn, focused on the forfeiture ramifications,

82 FR 34552 (2017) (taking official notice of Registrant's registration record in DEA's files and dismissing the OSC because Registrant's registration expired without a pending renewal application); *David M. Lewis, D.M.D.*, 78 FR 36591 (2013) (same); *Donald Brooks Reece II, M.D.*, 77 FR 35054, 35054 (2012) (taking official notice of Respondent's registration record in DEA's files and dismissing the OSC after Respondent's registration expired while the case was pending with the Administrator and after the ALJ recommended revocation because "Respondent's continued registration would be fully inconsistent with the public interest"); *James Edgar Lundeen, Sr., M.D.*, 77 FR 29696 (2012) (dismissing the OSC after taking official notice of Respondent's registration record in DEA's files, determining that Respondent's registration expired, and finding that Respondent did not file a renewal application).

<sup>11</sup> See *Meetinghouse Community Pharmacy, Inc.*, 74 FR 10073, n.10 (2009) (noting that Respondent was still in business and that controlled substances were seized, relied on *William R. Lockridge, M.D.* to affirm the ISO and "make clear" that the registration would have been revoked if it had not expired); *Nirmal and Nisha Saran, M.D./D.O.*, 73 FR 78827 (2008) (adjudicating the ISO/OSC as the best way to serve principles of judicial economy given Respondents' desire to remain registered); *Elmer P. Manalo, M.D.*, 73 FR 50353 (2008) (citing *William R. Lockridge, M.D.* as authority, but finding the ISO to be moot and dismissing the OSC because Respondent stopped participating in the proceeding and had not provided evidence of his intent to remain in professional practice or of any collateral consequence of the ISO); *Paul H. Volkanan*, 73 FR 30630 (2008), *correction*, 73 FR 32629 (2008) (adjudicating the renewal application and modification, but not following *William R. Lockridge, M.D.*); *RX Direct Pharmacy, Inc.*, 72 FR 54070 (2007) (dismissing the OSC as moot after the state license expired, the business closed, and no plan to re-enter the pharmacy business at some future date was evident, and stating that controlled substances seized pursuant to the ISO may be forfeited in any number of ways); *CRJ Pharmacy, Inc. and YPM Total Care Pharmacy, Inc.*, 72 FR 30846 (2007) (not adjudicating the ISO; revoking the registrations for lack of state authority).

<sup>12</sup> In *Robert Charles Ley, D.O.*, 76 FR 20033 (2011), for example, the ISO/OSC charged that Respondent had issued to undercover police officers numerous prescriptions for controlled substances lacking a legitimate medical purpose. Respondent allowed his registration to expire and DEA counsel moved to terminate the proceeding on the ground that the case was moot. Respondent's response to the termination motion stated that the summary suspension of his registration was "improper and unjustified" and that he did not object to the termination of the proceeding. The then-Administrator dismissed the ISO/OSC based on *Ronald J. Riegel, D.V.M.* while citing *William R. Lockridge, M.D.* as a "limited exception to the mootness rule." 76 FR at 20033.

if any, of seized controlled substances.<sup>13</sup> Thus, the reach of *William R. Lockridge, M.D.* was virtually narrowed to ISOs, and only ISOs for which the status of seized controlled substances had not been sufficiently resolved. In sum, the decisions in this period continued to exhibit a lack of uniformity.

In 2012 and thereafter, decisions “affirm” ISOs based on an analysis of the merits while indicating that there is no registration to revoke because the registration at issue had been allowed to expire.<sup>14</sup> *Ronald J. Riegel, D.V.M.*, 63 FR at 67,133. In 2015, an ALJ cited a regulatory provision, 21 CFR 1301.36(h), as a legal basis for not dismissing ISOs.<sup>15</sup> *Odette L. Campbell, M.D.*, 80 FR 41,062 (2015).<sup>16</sup> Citing this regulation, *William R. Lockridge, M.D.*, and *Meetinghouse Community Pharmacy, Inc.*, the ALJ concluded that “application of the mootness doctrine . . . is unwarranted and would deny

<sup>13</sup> See *Martin L. Korn, M.D.*, 79 FR 66406 (2014) (elaborating on, and agreeing with, *Quigley* that it is appropriate to dismiss an ISO/OSC when the Registrant does not respond and when he allows his registration to expire, acknowledging some of the collateral consequences originally identified in *William R. Lockridge, M.D.*, and explicitly noting that there is no issue to resolve concerning seized controlled substances); *Richard C. Quigley, D.O.*, 79 FR 50945 (2014) (dismissing the ISO/OSC as moot because Registrant did not answer the ISO/OSC, noting that no controlled substances had been seized, and finding that Registrant’s fleeing the country meant he did not intend to remain in professional practice, thus mitigating the concerns implicit in *William R. Lockridge, M.D.*’s original collateral consequences); *Tin T. Win, M.D.*, 78 FR 52802 (2013) (dismissing the ISO/OSC after the Registrant allowed her registration to expire and finding no collateral consequence because no controlled substances had been seized pursuant to the ISO); but see *Patricia A. Newton, M.D.*, 82 FR 26516, 26516 (2017) (dismissing the OSC after finding that there was “no showing of any collateral consequence which precludes a finding of mootness”).

<sup>14</sup> See *ChipRX, L.L.C., d/b/a City Center Pharmacy*, 82 FR 51433 (2017) (“affirming” the ISO after stating that there is neither a registration to revoke nor an application to act upon, addressing the merits, and ordering the forfeiture of all seized controlled substances); *S&S Pharmacy, Inc., d/b/a Platinum Pharmacy & Compounding*, 78 FR 57656 (2013) (“affirming” the ISO after addressing the merits, noting the existence of a federal court order that the registration be forfeited, stating that there is neither a registration to revoke nor an application to act upon, and ordering forfeiture of all seized controlled substances); *Darryl J. Mohr, M.D.*, 77 FR 34998, 34999 (2012) (“affirming” the ISO when Respondent allowed his registration to expire after the ALJ issued his recommendation that it be revoked, and finding the allegations “off the table” despite Respondent’s and DEA counsel’s arguments against mootness).

<sup>15</sup> “Any suspension shall continue in effect until the conclusion of all proceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Administrator or dissolved by a court of competent jurisdiction.”

<sup>16</sup> There is no indication that the Administrator adopted any part of the ALJ’s recommended decision even though it is attached in its entirety.

both Parties an opportunity to resolve the evidentiary issues, as well as prejudice the public interest. Additionally, there is no indication that Respondent intends to suspend her medical practice or not seek restoration of her registration.” *Id.* at 41,068.

Less than a week after publication of *Odette L. Campbell*, the then-Administrator again “affirmed” an ISO and ordered the immediate forfeiture of all seized controlled substances.<sup>17</sup> The practices of dismissing OSCs when the registration at issue was allowed to expire, and “affirming” ISOs when controlled substances had been seized and required a final disposition, continued.<sup>18</sup>

While I may find a proceeding moot in appropriate situations, the Government has cited no legal authority requiring me to do so when a registrant/respondent has allowed the registration at issue in an ISO/OSC to expire before issuance of a final decision. It is imperative to handle such expired registrations in a manner that is consistent with the Constitution, applicable legal authority, and sound law enforcement policy.

The U.S. Constitution does not mandate that I find mootness when a registrant/respondent allows the registration subject to an ISO/OSC to expire before issuance of my final decision. According to the case law, mootness is a product of Article III of the Constitution and the judicially-created prudential rules for federal courts. As the D.C. Circuit stated concerning Article III courts and mootness, the history of federal courts’ refusal to hear moot cases traces back to the common law notion that courts lack power to decide abstract questions when no dispute exists. *Tennessee Gas Pipeline v. Federal Power Comm’n*, 606 F.2d 1373, 1379 (D.C. Cir. 1979). More recently, also according to the D.C. Circuit, this “prudential rule has been raised to constitutional proportion, based specifically on the case or controversy requirement of Article III.” *Id.*

The D.C. Circuit cited the need for a “present, live controversy” to ensure avoidance of “advisory opinions on abstract propositions of law.” *Id.* It noted that the “case or controversy

<sup>17</sup> *Syed Jawed Akhtar-Zaidi, M.D.*, 80 FR 42,962 (2015).

<sup>18</sup> *Perry County Food & Drug*, 80 FR 70084 (2015) (affirming the ISO after taking official notice of a late-filed renewal application and vesting all right to forfeited controlled substances in the United States); *Victor B. Williams, M.D.*, 80 FR 50029 (2015) (dismissing the OSC as moot); *AIM Pharmacy & Surgical S. Corp.*, 80 FR 46326 (2015) (dismissing the OSC as moot).

requirement preserves the separation of powers by ‘assur(ing) that the federal courts will not intrude into areas committed to the other branches of government.’” *Id.* Finally, it noted that the mootness doctrine’s purpose also includes “limit[ing] the business of federal courts to questions presented in an adversary context and in a form historically viewed as capable of resolution through the judicial process.” *Id.*

Administrative agencies, such as DEA, however, do not exist by virtue of Article III. According to the D.C. Circuit, the different constitutional origins of Article III courts and administrative agencies mean that mootness does not play the same role in administrative agency adjudications as it plays in Article III court proceedings.

The subject matter of agencies’ jurisdiction naturally is not confined to cases or controversies inasmuch as agencies are creatures of [A]rticle I. Though agencies must act without arbitrariness, . . . still agencies are generally free to act in advisory or legislative capacities. While this is obvious in the case of rulemaking, it is also true where an agency proceeds via traditional adjudicatory forms of decision. Thus the Commission correctly observes that an agency may, if authorized by statute, issue an advisory opinion or abstract declaration without regard to the existence of an actual controversy. The . . . [APA] expressly permits such practices: The agency, with like effect as in the case of other orders, and in its sound discretion, may issue a declaratory order to terminate a controversy or remove uncertainty.

*Id.* at 1380 (citing 5 U.S.C. 554(e)); see also *Climax Molybdenum Co. v. Sec’y of Labor, Mine Safety and Health Admin.*, 703 F.2d 447, 451 (10th Cir. 1983) (“At the outset, we note that an administrative agency is not bound by the constitutional requirement of a ‘case or controversy’ that limits the authority of [A]rticle III courts to rule on moot issues.”).<sup>19</sup>

More recently, the Tenth Circuit, citing the D.C. Circuit, reaffirmed that administrative agencies are not bound by the constitutional requirement of a

<sup>19</sup> Federal courts’ recognition that Article III and judicially created gateway prudential rules are not binding on administrative agency adjudications not only applies to mootness, but also applies to advisory opinions and declaratory orders. *Americans for Safe Access v. Drug Enf’t Admin.*, 706 F.3d 438, 443 (D.C. Cir. 2013) (“An administrative agency, which is not subject to Article III of the Constitution . . . and related prudential limitations, may issue a declaratory order in mere anticipation of a controversy or simply to resolve an uncertainty.” (citing *Pfizer Inc. v. Shalala*, 182 F.3d 975, 980 (D.C. Cir. 1999))); *Metropolitan Council of NAACP Branches v. FCC*, 46 F.3d 1154, 1161 (D.C. Cir. 1995) (“[A]n agency may issue a declaratory order to terminate a controversy or remove uncertainty.”).

“case or controversy” that limits the authority of Article III courts to rule on moot issues. *RT Communications, Inc. v. FCC*, 201 F.3d 1264, 1267 (10th Cir. 2000). Further, according to the Tenth Circuit, an agency has “substantial discretion” to decide moot issues. *Id.* In exercising this discretion, according to that Court, the agency should be guided by two factors: “(1) whether resolution of the issue is the proper role of the agency as an adjudicatory body; and (2) whether concerns for judicial economy weigh in favor of present resolution.” *Id.* (citing *Climax Molybdenum Co.*, 703 F.2d at 451).

Even as to Article III courts, however, the Supreme Court rejected the strict application of mootness in a law enforcement context. In *United States v. W.T. Grant Co.*, 345 U.S. 629, 632 (1953), the parties agreed that “voluntary cessation of allegedly illegal conduct does not deprive the tribunal of power to hear and determine the case, *i.e.*, does not make the case moot.” 345 U.S. at 632. According to the Court, the controversy that may remain to be settled, even after cessation of the allegedly illegal conduct, is the “dispute over . . . [the challenged practices’] legality.” *Id.* The Court explained that a mootness determination could be appropriate, but only if the defendant met the “heavy” burden of demonstrating that “there is no reasonable expectation that the wrong will be repeated.” *Id.* at 633. Otherwise, because “say[ing] that the case has become moot means that the defendant is entitled to a dismissal as a matter of right, . . . [t]he courts have rightly refused to grant defendants such a powerful weapon against public law enforcement.” *Id.* at 632. The application of mootness, therefore, even by Article III courts, is not always appropriate.

I consider robust law enforcement and public safety to be paramount as I enforce the CSA, lead those who serve this Agency’s mission every day, and guide the registrant community’s compliance with the law.<sup>20</sup> As a

<sup>20</sup>In *Gonzales v. Oregon*, the Supreme Court addressed the scope of the CSA. 546 U.S. 243, 248–49 (2006). The case was filed after the U.S. Attorney General issued an Interpretive Rule stating that using controlled substances to assist suicide is not a legitimate medical purpose and, therefore, unlawful under the CSA. *Id.*

In ruling for Oregon, the Supreme Court stated that the main objectives of the CSA are to combat drug abuse and to control the legitimate and illegitimate traffic in controlled substances. *Id.* at 250. To accomplish these objectives, the Supreme Court stated, the CSA “creates a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession” of controlled substances. *Id.* (citing *Gonzales v. Raich*, 545 U.S.

corollary, it is inconsistent with robust law enforcement and public safety to allow a registrant/respondent “such a powerful weapon against public law enforcement” by allowing the registration at issue to expire and thereby bringing about the termination of ISO/OSC proceedings without a final decision. *Id.* Adjudicating OSCs/ISOs to finality allows DEA personnel to focus on conducting the most effective and efficient law enforcement work possible without the distraction of having to maneuver around the possibility of a mootness dismissal simply because they detected possible registrant wrongdoing too close to the expiration date of the registrant’s registration.

Further, final adjudications are particularly helpful in supporting the purposes of the CSA and my responsibilities to enforce the CSA because nothing in the CSA prohibits an individual or an entity from applying for a registration even when there is a history of being denied a registration, or a history of having a registration suspended or revoked. As such, having a final, official record of allegations, evidence, and the Administrator’s decisions regarding those allegations and evidence, assists and supports future interactions between the Agency and the registrant or applicant. Thus, these records and final decisions also support and facilitate my responsibilities under the CSA.

Next, concerning the regulated community as a whole, a final adjudication is a public record of the Agency’s expectations for current and prospective members of that community. Such a record helps all current and prospective registrants comply with the CSA and avoid ISOs/ OSCs. Further, similar to what has already been suggested, a final reviewable, or reviewed, decision provides the Agency, the registrant, and current and prospective members of the registrant community the additional benefit of circuit court correction and imprimatur. Circuit court review, and the lapsed possibility of circuit court review, enhance the authoritativeness of Agency decisions for all concerned.

Further, final adjudications inform the Executive Branch, the Legislative

1, 12–13 (2005)). The Court noted that part of this regime requires a physician, who wishes to prescribe controlled substances, to obtain a registration from the Attorney General, a function the Attorney General delegated to the DEA Administrator. *Oregon*, 546 U.S. at 251. The decision whether to issue, deny, suspend, or revoke a registration involves an evaluation of whether the physician’s having, or continuing to have, a registration is consistent with the public interest or is appropriate under other circumstances that the CSA articulates. *Id.*; see also 21 U.S.C. 823 and 824.

Branch, and the public about the Agency’s work, the CSA’s provisions, and the Agency’s CSA-related law enforcement activities. Final adjudications supply information to support those stakeholders’ duties and responsibilities concerning drug law enforcement. The stakeholders may then provide feedback to the Agency based on this information, thereby helping shape how the Agency carries out its responsibilities.

Lastly, final adjudications provide continuing education for all DEA personnel and help coordinate law enforcement efforts. They support efficient communications among law enforcement personnel because they contain information critical to how DEA personnel and their law enforcement partners are expected to meet law enforcement challenges and implement solutions.

In this matter, both an ISO and an OSC are at issue. Registrant’s Request makes clear that he has a “genuine overriding desire [to] be able to practice medicine once again.” Registrant’s Request, at 6. His decision to let his registration expire, therefore, does not reflect a commitment to leave the medical profession. After being served with OSC 1 and voluntarily surrendering it, Registrant applied for another registration. There is nothing to stop Registrant from doing the same in the future. Thus, I shall adjudicate OSC 2 to finality.<sup>21</sup> I reject the Government’s suggestion that this proceeding be dismissed as moot.<sup>22</sup>

I make the following findings of fact.

## Findings of Fact

### *Registrant’s DEA Registrations*

Registrant was previously registered with the DEA as a practitioner in schedules II through V under DEA COR BO2524204 at 901 Dover Drive, Suite 123, Newport Beach, California, 92660. GX 31 (Sworn DI Declaration dated October 21, 2016), at 2.

This COR was suspended pursuant to an Immediate Suspension Order, dated March 15, 2016 (OSC 1). *Id.* On March 18, 2016, after the Government served Registrant with OSC 1, he surrendered that COR. GX 17.

<sup>21</sup>The input that Registrant provided about his situation in Registrant’s Request does not control my analysis. Nevertheless, inasmuch as it indicates Registrant’s desire to practice medicine again, it certainly supports my decision to adjudicate OSC 2 to finality.

<sup>22</sup>At this time, I see no reason why my analysis of the constitutional origins of administrative agencies and of federal and Agency decisions addressing mootness would set me on a different course if, in the matter before me, only an OSC were at issue.

On May 20, 2016, Registrant submitted an application for a new COR. GX 18. Registrant answered in the negative to Question Two on the application, which reads “[h]as the applicant ever surrendered (for cause) or had a federal [COR] revoked, suspended, restricted or denied, or is any such action pending?” *Id.* Subsequently, on June 8, 2016, Registrant was issued a new COR, FO6043638, as a practitioner in schedules II through V at the registered address of 901 Dover Drive, Suite 123, Newport Beach, California, 92660. GX 25 (Registrant’s COR), at 1.<sup>23</sup>

On August 2, 2016, DEA issued OSC 2 concerning COR FO6043638. OSC 2, at 1. OSC 2 incorporated and attached OSC 1, and therefore, the facts included herein are derived from both OSC 1 and 2. *See* OSC 2, at 2; *see also* GX 26, at 7–12 (OSC 1).

#### *The Investigation of Registrant*

##### Undercover S.M.

On August 27, 2013,<sup>24</sup> an Irvine, California Police Department law enforcement officer acting in an undercover capacity (hereinafter, S.M.) visited the Registrant at his office and asked for an appointment, but was told that none was available. GX 31, at 2. Registrant asked S.M. whether he had “documentation to validate his injury,” and S.M. responded in the negative. *Id.* The Registrant then told S.M. that “the fee for an appointment would be \$400 if [S.M.] required a Schedule II medication.” *Id.* On August 29, 2013, S.M. returned to the office, where Registrant gave him a short physical examination for his “arm pain and numbness.” *Id.* They discussed S.M.’s lack of health insurance and lack of medical documentation and x-rays or MRIs, and Registrant urged S.M. to get an x-ray, but “[e]ventually, [Registrant] agreed to prescribe hydrocodone, stating that it ‘would still be crazy for me to do, but just cause I feel bad that you were here and I asked you to come back.’” *Id.* Registrant wrote a prescription for 30-ten milligram tablets of hydrocodone with one refill, which S.M. filled the

next day, and refilled on September 10, 2013. *Id.*

On September 24, 2013, S.M. visited Registrant at his office and audio recorded the interaction, which the Government provided along with a transcription certified by the DI. GX 2 (Transcription of Undercover Visit); GX 31, at 2; *see also* GX 1, at audio Enclosure 14 olson uc buy walk 9–24–13. S.M. told Registrant that he had “been taking the Roxys,<sup>25</sup>” and when Registrant asked him who prescribed them, S.M. told him “I’ve been taking them but not prescribed.” GX 2, at 2. Registrant then referred S.M. to a radiologist to obtain x-rays, and S.M. asked, “Am I able to get another set of Norcos in the meantime until I can get in?” *Id.* Registrant responded, “Uhhhh, yeah, yeah, yeah I’ll do that.” *Id.* However, when S.M. asked Registrant for “Roxys,” in addition to the “Norcos,” because the Roxys might show up on his drug test for a job interview, Registrant refused stating, “[I]t’s pretty liberal of me to even prescribe the pain medication without any real strong diagnosis,” and then described the scrutiny that he was under for controlled substances prescriptions. *Id.* at 4–5. When writing the prescription for the Norco, Registrant asked, “[H]ow many did I give you last time?” *Id.* at 7. S.M. replied, “I think you gave me 30 and a refill.” *Id.* S.M. received the prescription from Registrant for Norco, which he filled on September 25, 2013, and refilled on November 6, 2013. GX 31, at 3; *see also* GX 3 (prescription from Registrant to S.M. for a quantity of 30 “Norco tabs” 10 milligrams with one refill).

In sum, regarding S.M., I find that Registrant prescribed hydrocodone, or Norco, to S.M. on two different occasions with two refills, based on a minimal physical exam, without x-rays or pain assessments and knowing that S.M. was taking controlled substances that had not been prescribed.

##### Confidential Source K.B.

On February 13, 2015, a confidential source, K.B., audio/video recorded a visit with Registrant, a copy of which the government provided along with a transcription certified by the DI. GX 5 (Transcription of recorded interaction with K.B.); *see also* GX 1, at 02–13–uc–video.001 and 002. Registrant stated that he was “selective of taking new patients,” because “there’s a lot at stake

. . . particularly for the doctor,” so he had “to be really confident in who [he] take[s] . . . because [his] future is in their hands as well.” GX 5, at 2. K.B. told Registrant that she had “previously obtained prescriptions for controlled substances from a physician whose prescriptions had been declined by her pharmacy.” GX 31, at 3; GX 5, at 3. When K.B. told Registrant that she was on oxycodone and Xanax, he said, “See, it’s just, the more patients that I have that are on oxycodone, just the more attention I get from the DEA.” GX 5, at 5. K.B. identified the source of pain as being in her neck and shoulder, but the medical records she produced were for her lower back. *Id.* at 6–7. In response to Registrant’s questions about whether the pain was in her neck or her back, K.B. stated “[d]epends” and “[i]t’s up and down.” *Id.* at 10. Registrant stated that “sometimes people will come in and they think that the more painful things that they have, the more likely it would be that the [doctor]<sup>26</sup> would continue them on medications—that’s really not the case.”<sup>27</sup> *Id.* When K.B. repeated that her pain was in her shoulder and lower back, Registrant replied, “That’s my—that’s the point—you’ve got to be careful when you—doctors just kind of shut you out if you talk about too many spots.” *Id.* K.B. then said, “My shoulder more than my back,” but admitted that she did not have an MRI on her shoulder. *Id.* at 11, 13. Registrant asked K.B. to perform some basic movements and describe whether they hurt and stated, “See your range of motion is pretty good.” *Id.* at 11–12. The video recording demonstrated that Registrant remained behind his desk for his brief requests to K.B. to demonstrate movement of her arms and neck. GX 1, 02–13–uc video.001, at 29:52–30:45. Registrant told her that she needed an MRI on her shoulder despite her difficulty with insurance, because “[t]hey hold me to a standard of medical care . . . and so—I’m just exposed that way . . . unless people can find ways to at least get the minimum.” GX 5, at 14. Registrant continued stating, “Well . . . that’s the thing . . . you have a legitimate reason, but according to what you say . . . this MRI is kind of soft for . . . being on oxycodone—for long term.” *Id.* at 15.

<sup>23</sup> As noted previously, this COR expired on December 31, 2018. *See* GX 25.

<sup>24</sup> Although there is no supporting documentation demonstrating this encounter or the resulting prescription, nor any basis in the declaration for the DI’s knowledge of the encounter, I have no reason to doubt the veracity of the DI’s sworn Declaration, nothing in the record contradicts the DI’s Declaration, and further, the encounter the DI Declaration describes is consistent with the audio recording and transcript of the September 24, 2013 encounter in GX 1 and 2; therefore, I find the events as described by the DI to be facts.

<sup>25</sup> The DI’s Declaration asserts that “Roxys” refers to “Roxycodone, a brand name for the generic Schedule II controlled substances, oxycodone.” GX 31, at 2.

<sup>26</sup> Based on my review of the audio recording, I find that the transcription occasionally contains a scrivener’s error in using “Olsen” instead of “doctor.” *See, e.g.,* GX 1, 2015–02–13\_uc\_video.001, at 28:27.

<sup>27</sup> Throughout the transcripts, the DI used ellipses to depict pauses in the conversation. I have removed these and replaced them with dashes to prevent confusion between pauses and omissions of words from the quotations.

Registrant asked her if she had taken any other “meds” for “anxiety or depression,” and she responded that she was currently taking 2 milligrams of Xanax. *Id.* at 18. Later in the appointment, Registrant determined the dosage and quantity of the drugs he prescribed based solely on what K.B. requested. GX 5, at 22, 29; *see also* GX 31, at 3. Registrant also advised K.B. to not fill her prescription at a big chain pharmacy, because they “will just give you a big problem.” GX 5, at 29. While appearing to fill out her prescriptions, Registrant asked K.B. if she had ever been seen by a psychiatrist for [her] anxiety; she responded, “Yeah—I don’t think I have.” *Id.* at 29–30. As a result of this visit, Registrant prescribed K.B. 120 thirty-milligram tablets of oxycodone and 60 two-milligram tablets of alprazolam. GX 31, at 3; *see also*, GX 4, at 1 (copy of oxycodone and alprazolam prescriptions).

On March 9, 2015, K.B. returned to Registrant, and during an audio/video recorded conversation, she requested an increased dosage of oxycodone. GX 7, at 2. This visit was audio/video recorded, which the Government provided along with a transcription certified by the DI. GX 7, at 2 (transcript); *see also* GX 1, 17 UC 3.9.15 Olsen 3–9, 3–9(2). Registrant discussed surgery, which K.B. said she would consider after she could get insurance. GX 7, at 3. When asked, she told Registrant that she normally took 120 oxycodone, presumably, each month, and when he asked why she wanted “to go up,” she told him that she “need[ed] it.” *Id.* at 2. Registrant stated, “Well, I’ve been giv[ing] you 120 so I could give you 180,” to which K.B. replied, “Perfect. And then I don’t know if you do, do you do ADD?” *Id.* at 4. They discussed whether K.B. had taken Adderall before, and she said that she had, and that she wanted to try it because the oxycodone made her tired. *Id.* Registrant replied, “[I]t’s just kinda hard on the body being on an opiate and then a stimulant as well,” but he acquiesced. *Id.* K.B. reminded Registrant when writing the prescription to “put the Xanax on the one too” and “any chance you could go up to 90 on that?” referring to the prescriptions he was writing. *Id.* at 6; *see also* GX 1, 17 UC 3.9.15 3–9(2). Registrant told her that he “sure hate[d] to prescribe a lot of Xanax,” and she replied that she usually took it before bed to calm herself down. GX 7, at 6. Registrant told her “Xanax with oxycodone has been red flagged as associated with overdoses.” *Id.* Later, Registrant was determining how much Adderall to prescribe and he said, “Since I’m just starting you, I’ll give

you—uh—I think there’s 10, 20, and 30. . . .” K.B. replied, “I was doing 30’s once a day.” *Id.* at 10. Although Registrant expressed some concern about the potency, he prescribed K.B. thirty 30-milligram tablets of Adderall, one hundred and eighty 30-milligram tablets of oxycodone; and sixty 2-milligram tablets of alprazolam. GX 6 (copy of Adderall, oxycodone, and alprazolam prescriptions dated March 9, 2015).

In sum, regarding K.B., I find that Registrant repeatedly prescribed to K.B. multiple controlled substances, with limited physical examination, without assessing her pain or verifying the injuries, and in spite of drug seeking behavior.

Confidential Sources K.B. and J.W.

On April 9, 2015, K.B. returned to see Registrant, along with J.W., another confidential source. GX 10, at 1. This visit was audio/video recorded, which the Government provided along with a transcription certified by the DI. GX 1, at 2015–4–09\_uc\_video.001 and 002 (video); GX 10 (Transcription of recorded interaction with K.B. and J.W.). After introductions, Registrant reviewed K.B.’s prescriptions stating, “[W]e have oxycodone, Xanax, and Adderall.” *Id.* at 1–3. K.B. asked him, “[C]an we go . . . up to 200?” *Id.* at 4. Registrant answered, “No—I don’t want to go up.” *Id.* He told K.B., “[Y]ou have to set out the number you are going to allow yourself to have that day . . . and do it that way—otherwise you will always take more.” *Id.* K.B. told Registrant, “It just kind of helps me sleep,” and he responded, “Now—I get that, but . . . you’re taking the Adderall, so that’s going to work against that . . . and then you have the alprazolam should help you sleep.” *Id.* She then asked for something she could take “for sleeping.” *Id.* at 5. He responded, “[S]ee the thing is—you’re on three very big time drugs . . . [n]ow just to throw in another one.” *Id.* at 6.

K.B. then told Registrant she was taking the Adderall twice a day, and he noted “I’m only giving you thirty—‘[o]ne a day,’” and she admitted that she had been running out. *Id.* at 7. She replied, “I feel like when I was taking two it was good.” *Id.* Registrant advised her to break the Adderall in half, taking one-half in the morning and half at noon, and “shift [the Xanax] later.” *Id.* at 7–8.

Registrant then asked when she was taking the Xanax and she told him “first thing in the morning.” *Id.* at 8. He questioned why, and she said it made her “mellow.” *Id.* Finally, he told her, “I don’t really want to add another drug

. . . to this.” *Id.* at 10. K.B. agreed to “just do what we’re doing—[k]eep it simple.” *Id.*

Registrant told her that because she was “a new patient” she had to “stay in—the directions,” because it was “too dangerous” to have “people run out early—and having you—calling.” *Id.* He then counseled K.B. that one of the pitfalls of “medications is—um—you kind of start living like you should be in the mood to do everything—that you do,” and that “this kind of a “regimen[] kind of speaks to that—that—you also have to just kind of make yourself do stuff . . . [c]onsistently—or you don’t—mature really.” *Id.*

Registrant then asked K.B., “How’s your shoulder?” to which she responded, “Better.” *Id.* at 11. He then apologized for “lecturing” her. *Id.* at 11.

At this point, J.W. told Registrant that she went to school with K.B., and that K.B. “has failed to mention too is like—there has been a couple times where she has allowed me—cause I deal with anxiety, too—as well.” *Id.* at 11. Registrant then broke in and said, “She’s sharing her medicine.” *Id.* J.W. affirmed and told Registrant that the Xanax was helping her too and she didn’t want K.B. “to take all the heat for it.” *Id.* at 11, 12. J.W. also said, “So she’s been sharing some of the meds and like I’m an ex dancer as well—so like—I have some injuries, so it’s not just like—[K.B.] has been burning through everything.” *Id.* at 12. Registrant replied, “I guess I should have expected that . . . sometimes I’m a little naïve.” *Id.* J.W. then told Registrant she had injuries and asked if Registrant would consider “taking [her] on separately . . . since [she was] already here . . . .” *Id.*

Registrant stated, “[I]t is a good way to do it, I have to admit—is have somebody who I’ve seen bring in someone else and sort of endorse them—but no I just kind of met you.” *Id.* K.B. protested that they were “going on three months now,” and J.W. and K.B. then joked about relationships and told him they had brought “extra money, so we can pay you a little bit more—we’ll give you \$800.” *Id.* at 12–13. Registrant answered, “No I don’t want—I don’t want to get into doing that,” but then asked J.W. if her issues were “primarily anxiety? Or [p]lain?” *Id.* at 13. J.W. answered, “Both,” and agreed that they were similar problems to K.B. *Id.* J.W. told Registrant the Xanax was “good for [her]” at night, because she waitressed so she got “tense” (Registrant’s interrupted with the word), and then she discussed her ankle pain, which she claimed was caused by a fractured ankle in a skydiving accident several years before. *Id.* at 13–17.

Registrant asked if she was “taking medication?” *Id.* at 17. J.W. said she was taking “like probably 1 or 2,” and when Registrant asked if she was dependent on it she said, “No.” *Id.* K.B. told him, “She just doesn’t want to get it off the street,” and Registrant warned them that “strong pain medication like oxycodone is a way that you get kind of lured in.” *Id.* J.W. told Registrant that she could “have a bottle of prescription and not even touch it,” but since living with K.B., she “would just like dip into hers.” *Id.* at 18.

Registrant told K.B., “I know you kind of run out—but we found it’s another reason too,” and warned “it’s never a good thing when early and people are taking more than they should—or they run out.” *Id.* He then told them he had to focus while writing up the prescriptions. *Id.* at 19. After prompting from K.B., Registrant asked J.W. to fill out an initial visit form and one that “looks like a little contract.” *Id.*

Registrant asked K.B., “I’ve just been giving you one month at a time, right?” *Id.* at 23. She affirmed and asked, “Now if I wanted [two] refills or something like that, do I pay you more—or?” *Id.* at 24. Registrant responded, “This is what I do—I will do two months at a time and you just pay me a second \$100 for the second month.” *Id.* He explained that he would give a second prescription “to save people time and hassle coming in to see me,” but then added that “it’s not like I’ll do it for free—I still ask that they pay for the \$100 coverage for that month . . . because I still have to do everything that goes into covering these scripts—like they will call and verify and it’s . . . [i]t’s a big deal.” *Id.* Then he added, “[A]lthough to tell you the truth, that’s where I sometimes have problems. People do as they should, submit the second prescription when it’s time to submit it . . . Because pharmacies are on the lookout as well—they don’t want people getting their medication early.” *Id.* at 25.

Registrant also said, “[O]nce I get to know you, I’ll give a person more leeway. I’ll even go a third month as long as everything has been ok and you know I feel like I can trust you . . . then you know I’ll just work with you so that you get—you[re] covered.” *Id.* at 26.

Registrant asked J.W., “[W]hich ankle is it?” and “that’s by far the worst pain?” *Id.* at 31. J.W. told him she had a neck injury, too, from a back handspring accident, and that she had had an MRI that was “probably” in her files at home. *Id.* at 31–32. Registrant told her he would “love to see that” and it would be very helpful to see “x-rays of [her] ankle—just some of the background of [her] injuries.” *Id.* at 32.

He added, “In fact it’d be essential.” *Id.* He asked when the injuries occurred, and about the symptoms of her neck injury, and if she had any other medical problems. *Id.* at 32–35. When Registrant repeated that J.W. had “been using some of [K.B.]’s oxycodone,” J.W. responded, “Yeah, oxycodone, her Xanax and I’m taking Adderall for studying too.” *Id.* at 35.

Registrant told J.W. he had to “decide where to start [her] in terms of medication . . . you want to take as little as you can get by with—first of all—that’s just important.” *Id.* at 36. He added he was going to start her off at 15mg strength oxycodone, because the 30 mg was “the strongest pain pill you can take” and “for [him] to just start [J.W.] off on that would be bad medicine.” *Id.*

K.B. suggested “15 and then 60?” and Registrant stated, “So I give you the 15 and I’ll give you like 60 of them, so you can have the—you know—one to two as needed . . . and we’ll just see how it goes with that.” *Id.* at 37. While writing J.W.’s prescription, Registrant told her he was “going to put your neck injury here—it’s just—it’s more of a potentially serious injury.” *Id.* at 39. J.W. replied, “Ok—whatever you think is best—I trust you—whatever you tell me to do.” *Id.* He added that he chose “the 15mg, cause most pharmacies will have that—oh, if they have oxycodone, they’ll have this one.” *Id.* He then decided to give her 90 [tablets] to start instead of 60, because it “gives you a little bit more value for your money.” *Id.*

K.B. asked if Registrant could mail a prescription for a second month (presumably of oxycodone), and they agreed K.B. could pay for the prescription at this visit and Registrant would mail the prescription to her. *Id.* at 41.

Registrant then turned to the Adderall prescription for J.W., and she said, “It helps with school—it really does.” *Id.* He told J.W. that he would “give [her] 30 of those and just take ½ to 1 tab.” *Id.*

J.W. then left the office to use the bathroom, and after chatting a bit, Registrant asked K.B. (presumably referring to J.W.) “[S]he takes the alprazolam, right?” *Id.* at 43. K.B. answered, “Yeah—I’d do like 60,” and Registrant replied, “Yeah—thanks.” When J.W. returned, he told her he was giving her “the one milligram Xanax—rather than the 2,” because he was starting her off. *Id.* at 43–44. Registrant finished writing prescriptions for both women, which he gave to J.W. and told her “just be really careful with the medication—just really respect it.” *Id.* at 47.

Registrant issued to J.W. a prescription dated April 9, 2015, for 90 oxycodone 15mg, listing the diagnosis as “Dx Cervical Disk.” GX 8, at 1. He also issued her a prescription for 30 Adderall tabs 30mg, listing ADHD as the diagnosis, and a third prescription for 60 alprazolam 1 mg, listing the diagnosis as “Anxiety/Insomnia” and authorizing 1 refill. GX 8, at 2–3.<sup>28</sup>

At the same visit, Registrant issued a prescription to K.B. for 30 Adderall tabs 30mg with a diagnosis of “Rotator Cuff/ADHD.” GX 9, at 1. He also issued a single prescription, with the diagnosis of “Rotator Cuff Tear [L] Shoulder,” which included 180 oxycodone 30 mg, and 60 alprazolam 2mg for “Severe Anxiety/Insomnia.” *Id.* at 2. On the same date, April 9, 2015, Registrant issued to K.B. another prescription for 30 Adderall 30mg for “Attention Deficit Dys,” which includes a note “Release date April 30, 2015.” GX 11, at 1. Registrant wrote another prescription, also dated April 9, 2015, and noting “Release April 30, 2015,” for 180 oxycodone 30mg for “severe pain,” 60 alprazolam 2mg “PRN Anxiety,” and 60 Naproxen 550 “PRN Inflammation/Pain” with a diagnosis “C/S Disk [ ] Rot Cuff Tear [.]” *Id.* at 2. The Government’s evidence also includes a copy of an envelope bearing a postmark of April 17, 2015, Registrant’s name and return office address at 901 Dover Drive, Suite #123, Newport Beach, California, and addressed to K.B. in Las Vegas, NV 89101. GX 12. Although the DI does not state the origin of the envelope, at the undercover meeting, K.B. discussed Registrant mailing her second prescriptions. *See* GX 10, at 45.

On April 28, 2015, J.W. returned to Registrant’s office alone. This visit was audio/video recorded, which the Government provided along with a transcription certified by the DI. GX 14 (Transcription of recorded interaction with J.W.); *see also* GX 1, 24 UC 4.28.15, 0431.001–003. Registrant greeted her and asked, “How’d it go with the medication the past few weeks?” GX 14, at 1. J.W. replied that it “went well” but then told him that K.B. had left town, and J.W. “gave [K.B.] some of [J.W.’s] because she ran out before she left and she didn’t know if she’d be able to get the script from [Registrant] . . . That’s why [J.W.] came in so much earlier for a refill.” *Id.* Registrant said, “Right . . . I owed her one.” *Id.*

<sup>28</sup> Registrant did not include an address on any of the prescriptions to K.B. or J.W., which would constitute a violation of 21 CFR 1306.05(a), but neither OSC alleged this violation, so I am not basing my findings on these violations. *See e.g.*, GX 8, GX 11, GX 13.

She told him she was taking the “smaller Oxy’s” and was taking them more often, and asked, “[I]s there any way just so I won’t have to take them as frequently?” *Id.* at 3. Registrant replied that it was “bad form to start with the highest dose” in the initial prescription, but he could “bump it up now.” *Id.* Registrant then stated he had given her “90 last time so I’ll give you 90 of the 30 milligram.” *Id.* at 5. J.W. repeated that she had given K.B. “half of them before she left town.” *Id.* Registrant said, “I see,” but added he had already written “the 90” and that he “still owe[d] her,” but that he thought the prescriptions were sent out. *Id.* He added, “And um you guys can just settle up.” *Id.*

Registrant then inquired, “[s]o the [o]xycodone and then the Adderall and the alprazolam, right?” to which J.W. agreed. *Id.* at 6. He told her he was giving her 30 tablets of 30-milligram Adderall, which “is the max dose” and 1 milligram of Xanax. *Id.* at 7. J.W. said she thought [K.B.] got “the 2’s” and began to ask if Registrant “fe[lt] comfortable with, sorry, I hope you don’t mind . . .” *Id.* Registrant interrupted, “No, it’s okay I don’t mind. It’s just when you first write a prescription for somebody it just looks bad to like hit them with the highest dosage.” *Id.* at 8. Finally, Registrant told her she owed “just 100” and that the \$400 was just the initial fee. *Id.* at 11. He also told her that he didn’t “put a refill on the [a]lprazolam,” because he would need to see her the following month. *Id.* He took a picture of the prescriptions using his cellphone, which he said he forwarded to his daughter, “so she can validate them with the pharmacist.” *Id.* at 11–12.

J.W. then asked for a receipt, and if she could “come back a little earlier than the month,” if she needed to. *Id.* at 12–13. Registrant agreed that J.W. had “a little bit of [a] situation,” likely referring to the uncertainty of K.B.’s return, and added, “I’ll take care of you.” *Id.* at 13. Registrant told her, “100—uh—charge we’re gonna go with cash so . . .” *Id.* at 14. J.W. handed \$100 cash to Registrant, who then obtained her email address to email her receipt, and the visit concluded. *Id.*

The Government’s evidence included copies of three prescriptions issued to J.W. by Registrant on April 28, 2015; one for 90 oxycodone 30mg for a diagnosis of Cervical Disk w/[ ], another for “Anxiety” for 60 alprazolam 2mg tab<sup>29</sup> and the third for “DX-ADHD” for 30 Adderall 30mg. GX 13, at 1–3.

<sup>29</sup> There is no date on this prescription, but the Government did not allege violations of the CSA

On January 20, 2016, J.W. returned to Registrant’s office to obtain refills of her prescriptions. GX 31, at 4; GX 16, at 1–5. This visit was audio/video recorded, which the Government provided along with a transcription certified by the DI.<sup>30</sup> GX 16, at 5 (Transcription of recorded interaction with J.W.); GX 24 (CD containing audio/video recording [Olsen\_Buy\_Walk\_1–20–16.005], transcript and DEA 6—Report of Investigation).

According to the recording and the transcript, Registrant noted that he had not seen J.W. “in a while,” and she told Registrant that she had been living in Monterey and “just came back in town again” and she “usually come[s] back for like 6 months at a time . . . so [she]’ll probably see [Registrant] more regularly now.” GX 16, at 1. Registrant said, “I was giving you before, I guess, oxycodone . . . and alprazolam and Adderall,” and later asked “do you just make these last longer or . . . [d]id you see other doctors?” *Id.* J.W. replied, “Up in Monterey? Yeah, I don’t have any of his stuff on me right now.” *Id.* at 2. Registrant then told her that the other doctor would appear on her CURES (Controlled Substance Utilization Review and Evaluation System) report, and explained that report to her. *Id.* He told her to “be a little careful with that,” but that “it’s fine,” because “[she] didn’t know probably if [she was] going to come back.” *Id.*

Registrant then asked her, “[S]o . . . exactly what I did before—oxycodone 30 mg #90 . . . Alprazolam 2mg #60/ . . . Adderall 30mg[?]” *Id.* J.W. asked, “If you can you give me something that will last me a little longer and then I’ll come back in February—I mean end of February.” *Id.* at 3. Registrant told her he could “give [her] 120 oxycodone” and warned “you just have to be careful.” *Id.* According to the video, while J.W. and Registrant talked, he remained seated behind his desk writing and referring to paperwork. GX 24, at Olsen\_Buy\_Walk\_1–20–16.005 at 26–37. He asked, “Your main pain problem—was it your lower back?” GX 16, at 4. J.W. told him it was an “ankle issue and then a neck as well,” and he responded, “[o]h, cervical is what I put.” *Id.* at 4. He then asked “Does this control your pain pretty well?” and she replied “[y]eah—it’s good for sleeping.” *Id.* He then told her, “It’s \$150,” which she paid and he texted her a receipt. *Id.*

regulations, so I will not include it in my findings of fact.

<sup>30</sup> The oath states that the visit occurred on 4/28/15, but the DI signed and dated the transcription on January 22, 2016, thus I find the date April 28, 2015 to be a scrivener’s error.

at 4–5; *see also* GX 24, Olsen\_Buy\_Walk\_1–20–16.005, at 36:26–37:11.

The Government’s evidence includes copies of three prescriptions issued by Registrant to J.W. on January 20, 2016: “Adderall tabs 30mg #30;” “Alprazolam tabs 2.0mg 60 1 tab . . . severe anxiety;” “Oxycodone tabs 30mg 120 . . . Severe pain (Max 4/day).” GX 15, at 1–3.

In sum, regarding K.B. and J.W., I find that Registrant issued both of them multiple prescriptions for several controlled substances, conducted no physical examinations or pain assessments, changed J.W.’s primary injury to justify controlled substance prescription, and ignored drug seeking behavior for both J.W. and K.B., including that K.B. was sharing her medication and that J.W. had been prescribed unknown quantities of medication by another doctor.

#### B.H. Records

OSC 2 also alleged prescribing below the standard of care for B.H. and M.C., whose medical records were seized as a result of the execution of a criminal search warrant at Registrant’s registered address. <sup>31</sup> GX 31, at 5. From the evidence seized, the DI identified B.H., to whom Registrant had issued prescriptions for controlled substances, including “oxymorphone, carisoprodol, oxycodone, alprazolam, on at least 29 different occasions. For example, [Registrant] issued a prescription for 120-forty milligram tablets of oxymorphone, 180-thirty milligram tablets of oxycodone” and 30 two-milligram tablets of alprazolam on the same day.<sup>32</sup> *Id.* at 6; *see also* GX 20, at

<sup>31</sup> OSC 2 lists the date of the search warrant as March 16, 2016, but the rest of the evidence, including the Declaration and the Registrant’s Voluntary Surrender points to the date as being March 18, 2016. *See* GX 17; GX 31, at 5. I otherwise find the DI Declaration credible that the search warrant was conducted and that it resulted in the seizure of these records, so I am not including the date, but am relying on the submitted evidence.

<sup>32</sup> OSC 2 and the DI Declaration also allege that in addition to these medications, Registrant prescribed “two different prescriptions for 30 two-milligram tablets of alprazolam.” GX 31, at 6; *see also* OSC 2, at 2. OSC 2 states that this transaction occurred on March 16, 2016; however, the Government’s evidence includes only one prescription for alprazolam on that date. GX 31, at 6; *see also* OSC 2, at 2; *but see* GX 20, at 12, 14 (showing one prescription for 60 tablets of 2-milligram alprazolam on February 23, 2016, and one prescription for 30 tablets of 2-milligram alprazolam on March 16, 2016). It appears that the mistake may have been made using the Dr. Munzing’s list of B.H.’s prescriptions, where he includes the correct prescription amounts, but mistook the date for the first 60 tablet prescription. GX 32, at 10. Dr. Munzing makes no further findings related to the double prescription, so I am deeming the error to be nonessential to the Government’s case. Had it been included in the OSC, it appears that B.H. could not have possibly

Continued

16, 18, 14. Additionally, Registrant issued a new prescription for 120 forty-milligram tablets of oxymorphone to B.H. on July 6, 2016, after Registrant surrendered his previous COR following the issuance of OSC 1 and obtained a new COR. *Id.*; see also GX 20, at 19.

The DI also declared that the search warrant did not reveal any record of the “patient’s chief complaint or vital signs,” or “of any medical history or examination,” or “progress notes or treatment plan.” GX 31, at 5. The DI stated that “[e]lectronic records indicated that B.H. was a ‘new patient’ on January 15, 2015, and had been referred by another physician who ‘was working on a plan to get [B.H.] off of meds slowly.’” *Id.* Further, the DI stated that the electronic files included a note about a “dirt bike injury L5 S1” and “previous shoulder surgeries.” *Id.* According to the DI, the only paper records that were found were prescriptions and a pain agreement. *Id.* GX 22 (seized prescription paper records). The Government’s evidence includes prescriptions issued to B.H.<sup>33</sup> for multiple controlled substances on six different dates. See GX 20, at 1, 2 (Prescription for oxycodone, two for oxymorphone, and one for carisoprodol issued August 11, 2015); at 3 (oxycodone November 24, 2015); at 5, 6 (oxymorphone, oxycodone and alprazolam issued December 22, 2015); at 7, 8 (oxycodone, oxymorphone and

exhausted his supply of 60 tablets by taking 2 per day for 22 days (B.H. could have been diverting them), but I make my findings based on the other evidence presented on B.H.

It does appear from the records submitted that Registrant issued two prescriptions on the same day for varying amounts of 40 milligram oxymorphone tablets with no release date, but neither the OSC, nor Dr. Munzing included allegations regarding the double prescribing of oxymorphone, so I will not include it in my findings of fact. GX 20, at 1&2.

<sup>33</sup> In the vast majority of the prescriptions to B.H., the Registrant did not include an address, which would also constitute a violation of 21 CFR 1306.05(a). It also appears that as a result of this empty address, B.H. was able to fill prescriptions from multiple different pharmacies, using different addresses, potentially in an attempt to avoid detection by law enforcement. See e.g., GX 20, at 5&6 (demonstrating that B.H. used two different addresses and two different pharmacies to fill Registrant’s prescriptions dated December 22, 2015). Because the regulatory violation was not charged in either OSC, I am not including that charge in my findings, but OSC 2 does note that B.H.’s utilization of multiple pharmacies to fill his prescriptions was a red flag indicating drug abuse and/or diversion, so I believe that Registrant had adequate notice that the Government was charging him with B.H.’s indications of drug abuse/diversion, one of which is using multiple addresses, and so I include that fact herein.

alprazolam issued January 25, 2016); at 9, 11, 12 (oxycodone and two different prescriptions for oxymorphone and alprazolam issued on February 23, 2016); at 14, 16, 18 (alprazolam, oxycodone, oxymorphone issued March 16, 2016); at 22 (oxycodone issued on July 6, 2016).

In sum, regarding B.H., I find that Registrant issued multiple prescriptions for several controlled substances to B.H., and it appears from Registrant’s records that Registrant did not conduct physical examinations, pain assessments, did not obtain documentation of B.H.’s injuries and ignored red flags for diversion/abuse.

#### M.C. Records

OSC 2 also includes allegations related to prescribing below the standard of care related to M.C. based on the records obtained from the search warrant. OSC 2, at 3. The DI reviewed the prescriptions for M.C. and determined that Registrant had issued prescriptions for controlled substances, including oxycodone, hydrocodone and alprazolam, on 14 different occasions from June 2015 to July 2016. GX 31, at 6. “For example, on February 18, 2016, [Registrant] issued prescriptions to M.C. for 240 thirty-milligram tablets of oxycodone and 180 ten-milligram tablets of hydrocodone” and 90 two-milligram tablets of alprazolam.<sup>34</sup> *Id.*; see also GX 19, at 20, 18, 15. (M.C. prescriptions). Additionally, Registrant issued prescriptions to M.C. for hydrocodone and oxycodone on July 1, 2016, after Registrant had surrendered his first COR and obtained his new COR. GX 31, at 6; see also GX 19, at 22 (prescription). The Government included prescriptions for multiple controlled substances issued to M.C. on six different dates in its exhibits. See GX 19, at 1 (Prescription for hydrocodone and alprazolam issued February 25, 2015); at 2, 4 (oxycodone and hydrocodone June 16, 2015); at 6, 8 (oxycodone and hydrocodone issued August 26, 2015); 10 (testosterone September 21, 2015); at 11, 13

<sup>34</sup> Again, it appears from the evidence that the DI made a mistake about the existence of two prescriptions for alprazolam. See OSC 2, at 3; see also GX 31, at 6. The evidence demonstrates that there was one refill, which might have been the source of the confusion. GX 19, at 17. Once again, there is no finding related to this, nor is there any indication in Dr. Munzing’s declaration, so I am not sustaining any allegation on the double prescription and I am basing my findings on the other uncontroverted evidence.

(oxycodone and hydrocodone issued December 16, 2015); at 15, 18, 20 (alprazolam, hydrocodone, and oxycodone issued February 18, 2016); at 22 (oxycodone and hydrocodone issued July 1, 2016 (after he had surrendered his first COR and obtained a new COR)).

The DI declared that the electronic records for M.C. stated that he was diagnosed with “chronic pain syndrome,” but there were no records of the chief complaint, vital signs, medical history, physical examination, progress notes or treatment plan. GX 31, at 5. The DI included the only three paper records seized related to M.C., which consisted of two prescriptions and a note documenting “chest pain.” *Id.*; see also GX 21 (three paper records on M.C.).

In sum, regarding M.C., I find that Registrant issued multiple prescriptions for several controlled substances to M.C. and it appears from Registrant’s records that Registrant did not conduct physical examinations, pain assessments, did not obtain documentation of M.C.’s injuries and ignored red flags for diversion/abuse.

The Government Expert’s Review of Registrant’s Prescribing to S.M., K.B. and J.W.

Dr. Munzing, the Government’s Expert, is a physician licensed and practicing in the State of California, who has more than three decades of clinical work and who has served as a Medical Expert Reviewer for the Medical Board of California.<sup>35</sup> GX 32, at 1 (Declaration of Dr. Munzing); see also, GX 23 (Dr. Munzing’s Curriculum Vitae). I find that Dr. Munzing is an expert in standard of care for prescribing controlled substances in California and I give his report full credit.

Dr. Munzing concluded, and I agree, that with regard to the controlled substances prescribed to S.M., K.B., and J.W., and M.C. and B.H., Registrant’s actions “were both dangerous and reckless and fell far below the acceptable standard of care in the State of California.” *Id.* at 7 (S.M., K.B., and J.W.); see also 10 (related to M.C. and B.H.). He relied in part on the standard of care in California, as described in the *Guidelines for Prescribing Controlled Substances for Pain* (Medical Board of

<sup>35</sup> Currently named California Department of Consumer Affairs, Division of Investigation, and Health Quality Investigation Unit (“HQIU”). GX 32, at 1.

California November 2014<sup>36</sup>)<sup>37</sup> (hereinafter, “the Guidelines”). *Id.* He declared that the Guidelines state that “at a minimum, a physician must complete a medical history and physical examination.” *Id.* (citing Guidelines, at 9). Dr. Munzing attested that the Guidelines also set the standard that a physician “should perform a psychological evaluation that includes the risk of addictive disorders”; “should establish a diagnosis and medical necessity based on reviewing past medical records, laboratory [studies], and imaging studies”; “should also order new studies if necessary”; should “employ screening tools such as scales that measure pain intensity and interference”; “should also explore non-opioid therapeutic options”; “should evaluate the potential risks and benefits of opioid therapy, remain cognizant of aberrant or drug seeking behaviors, and review CURES data to monitor such behavior.” GX 32, at 7 (citing the Guidelines, at 9–10).

Dr. Munzing also based his conclusions on California law, specifically California Health and Safety Code § 11153(a),<sup>38</sup> which “states that a prescription for [a] controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice[.]” *Id.* at 7 (citing Cal. Health & Safety Code § 11153(a) (West 2019)). He also referenced California Health and Safety Code Section 11154(a), which “states

<sup>36</sup> It is noted that these guidelines were published in November of 2014 and Registrant saw S.M. in 2013; however, Dr. Munzing also based his opinion on the Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeon’s 2013, which he identified as the 7th Edition. GX 32, at 8. Upon review of the guide, it does not state a particular date of publication, but the portions of the guide on which he relies are statutory and preexisted 2013. See <https://www.mbc.ca.gov/Download/Documents/laws-guide.pdf>. Because the California laws on which Dr. Munzing relied for his assessment of the standard of care, were in existence at the time of S.M.’s visit to Registrant, I find that the fact that Dr. Munzing relied in part on guidelines that were issued after S.M.’s visit does not affect his overall assessment that Registrant’s prescribing to S.M. was below the standard of care in California. I have not considered Dr. Munzing’s bases that appeared to rely on the 2014 Guide, but I believe that his underlying finding that the prescription was not issued for a legitimate medical purpose and that there was no physical examination as required by California law demonstrates that Registrant’s prescribing to S.M. fell below the standard of care in California. See GX 32, at 5.

<sup>37</sup> Although the Government’s evidence did not include the Guidelines, they are publically available at: [http://www.mbc.ca.gov/Licensees/PrescribingPain\\_Guidelines.pdf](http://www.mbc.ca.gov/Licensees/PrescribingPain_Guidelines.pdf).

<sup>38</sup> In citing the California code sections, Dr. Munzing cited to 1153(a) and 1154(a) instead of 11153(a) and 11154(a); however, I find that this merely to be a scrivener’s error. See G.X. 32, at 7.

that no person shall knowingly prescribe or furnish a controlled substance to any person not under his treatment for a pathology or condition.” *Id.* (citing Cal. Health & Safety Code § 11154(a) (West 2019)). He concluded, and I agree, that Registrant “failed to adequately identify a pathology or condition that would justify the prescribing of controlled substances.” *Id.* Additionally, Dr. Munzing “considered California Business and Profession[s] Code §§ 2242 (prescribing without an appropriate prior examination and medication indication); 2241 (prescribing to a person presenting him/herself as an addict); 2234 (defining ‘unprofessional conduct’ as an act of gross negligence, repeated negligent acts, or incompetence); and 725 (repeated acts of clearly excessive prescribing).” *Id.* at 7.

Dr. Munzing also based his conclusions on the “Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons” published by the Medical Board of California, 7th Edition 2013 (hereinafter, “the Physician’s Guide”), which, in his opinion, further sets out the applicable standard of care in California. *Id.* at 8. According to him, the Physician’s Guide explains that when prescribing controlled substances for the treatment of pain, a practitioner must perform a sufficient physical examination and take a medical history. *Id.* at 8. (citing Cal. Health & Safety Code §§ 11150, 11154 (West 2019)). “The practitioner must make an assessment of the patients’ pain, their physical and psychological function, and their history of prior pain treatment.” *Id.*

The practitioner must also make an assessment of any underlying or coexisting diseases or conditions and order and perform diagnostic testing if necessary. [Citing the Guide at 57]. Finally, the practitioner must adequately discuss the risks and benefits of the use of controlled substances and any other treatment modalities; periodically review the course of pain treatment or gather any new information about the etiology of the patient or the patients’ state of health, and give special attention to patients, who, by their own words and actions, pose a risk for medication misuse and/or diversion.

*Id.* Finally, Dr. Munzing continued, the Physician’s Guide mandates that a physician should “keep accurate and complete records which document the items listed . . . including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medication, rationale for changes in the treatment plan or medications, agreements with the

patient, and periodic reviews of the treatment plan.” *Id.* at 8 (citing the Physician’s Guide, at 59). “The [Physician’s] Guide also states, “[p]ain levels, levels of function, and quality of life should be documented.” *Id.* (citing the Physician’s Guide, at 59).

According to his sworn Declaration, Dr. Munzing reviewed the audio recording of S.M.’s undercover visit on September 24, 2013, and a copy of the prescription issued at that visit. GX 32, at 1–2. He concluded, and I agree, that S.M. presented “numerous red flags” for diversion, including that on September 24th, he had specifically asked for “Roxys” and “further indicated he had been taking oxycodone illegally and was afraid it would show up in a drug screen.” *Id.* at 4–5. He also found that Registrant failed to take an appropriate current medical history, review S.M.’s past medical history, and take S.M.’s vital signs. *Id.* at 5. He also opined, and I agree, that Registrant “performed a minimal, substandard physical examination” during the first visit only, that “he failed to determine the patient’s current or past alcohol and/or drug use and/or abuse,” and that “he failed to note the patient’s pain level or functional level.” *Id.* He also noted that no imaging was ordered on the first visit and no prior images were provided to Registrant by the patient, and that “there was no indication that [Registrant] ordered any other tests, made any referrals, explored any alternatives to controlled substances, or checked to see [S.M.’s] prescription history on the state prescription monitoring program CURES.” *Id.* Finally, Dr. Munzing opined, and I agree, that Registrant “prescribed hydrocodone based on feeling sorry for the patient and not for any legitimate medical reason.” *Id.*

Regarding K.B.’s February 13, 2015, and March 9, 2015, appointments, Dr. Munzing concluded, and I agree, that K.M. had demonstrated numerous indicia of diversion, which were ignored by Registrant. *Id.* According to Dr. Munzing these red flags included that: She admitted she had obtained prescriptions that were declined by a pharmacy; she complained of neck and shoulder pain, but the MRI she presented was of her lower back; and, she requested Adderall, a third controlled substance and an increase in oxycodone, without offering any legitimate medical reason on her second visit. *Id.* For both visits, Dr. Munzing determined that Registrant took a minimal, but inadequate current medical history, as well as past medical history; failed to take vital signs; “performed only a minimal, but

inadequate, physical examination” on the first visit (and none on the second visit); failed to determine past alcohol and/or drug use and/or abuse; and failed to note the pain level or functional level. *Id.* No controlled substance agreement was signed, urine drug tests ordered, and there was only “minimal but inadequate discussion about the risks and benefits of controlled substance use.” *Id.* Further, Dr. Munzing concluded that Registrant had not “ordered any other tests, made any referrals, or checked to see the patient’s prescription history on CURES.” The diagnosis of anxiety justifying the prescription for alprazolam, “was not based on any evidence gathered during the visit.” *Id.* Dr. Munzing concluded, and I agree, that the controlled substances prescribed to K.B. on March 9, 2015, “were not prescribed for a medically legitimate purpose.” *Id.* at 6.

Dr. Munzing concluded, and I agree, that on April 9, 2015, J.W. and K.B. demonstrated further indicia of diversion. *Id.* Specifically, K.B. requested an increase in oxycodone and admitted that she had abused the oxycodone that had been prescribed by increasing her dosage. *Id.* J.W. admitted that “she had obtained alprazolam and oxycodone from K.B.” *Id.*; see also, GX 10, at 11–12. K.B. mentioned that J.W. obtained controlled substances “off the street” and J.W. discussed filling her prescriptions at out-of-state pharmacies. GX 32, at 6; see also GX 10, at 17. Additionally, Dr. Munzing concluded, and I agree, that on April 28, 2015, J.W. admitted diverting controlled substances when she stated that she was sharing medication with K.B., and exhibited other drug seeking activity by requesting a higher dose of oxycodone without providing a medical justification, and without providing any documentation of her injuries. GX 32, at 6. Dr. Munzing concluded that J.W. demonstrated further indicia of abuse or diversion that Registrant ignored, including, obtaining controlled substances from multiple providers; asking for an increased quantity of oxycodone; and telling Registrant that oxycodone was “good for sleeping.” *Id.* For all of the visits with J.W., including the joint visit with K.B., Dr. Munzing found that Registrant took no current or past medical history, failed to take vital signs, “performed no physical examination,” failed to determine past alcohol and/or drug use and/or abuse, and failed to note the patient’s pain level or functional level. *Id.* According to Dr. Munzing, no urine drug tests were ordered, and no imaging was provided or ordered. *Id.* Further, Dr. Munzing

determined, “There is no indication that [Registrant] ordered any other tests, made any referrals, or checked to see the patient’s prescription histories on CURES.” *Id.* at 6–7.

Dr. Munzing also reviewed the prescriptions and medical records for M.C. and B.H. that were included in the Government’s evidence and reviewed the CURES reports for these individuals. *Id.* at 8–10. In reviewing the medical records for M.C. and B.H., Dr. Munzing opined that there was no record of any medical history or examination, pain history, progress notes, or treatment plan for either patient. *Id.* at 9, 10. He also found that there was no legitimate diagnosis on which to base the prescriptions. *Id.* at 9 (finding that M.C.’s “chronic pain syndrome” is not a legitimate medical diagnosis); see also *id.* at 10. Furthermore, he identified numerous indicia of abuse and/or diversion, such as, B.H. and M.C. utilized multiple pharmacies, received dangerous prescription cocktails (both received opioids along with benzodiazepines), received high doses of opioid medications. Additionally, B.H. drove long distances, and M.C. did not fill prescriptions until several weeks after they were written. *Id.* at 11.

Dr. Munzing further concluded, and I agree, that Registrant “failed to adhere to the above-described California requirements for prescribing controlled substances for pain,” and that “to the extent that [Registrant] attempted to comply with some of the requirements, his attempts fell far below the acceptable standard of care.” *Id.* at 8 (related to S.M., K.B., and J.W.). He further concluded that Registrant’s “treatment of M.C. and B.H. was both dangerous and reckless and fell far below the standard of care for prescribing controlled substances in the State of California.” *Id.* at 10. He concluded, and I agree, in summary, that it was his “professional opinion that the prescriptions issued to S.M., K.B., J.W., M.C. and B.H. lacked a legitimate medical purpose and were issued outside the usual course of professional practice.” *Id.* at 11.

#### *Allegation That Registrant Issued Prescriptions for Controlled Substances Outside the Usual Course of the Professional Practice*

Having read and analyzed all of the record evidence, I agree with and incorporate the conclusions of Dr. Munzing and find that the record contains substantial evidence that Registrant prescribed controlled substances outside of the usual course of the professional practice in California. See GX 32, at 11. In

particular, Dr. Munzing stated that the Guide requires that a practitioner prescribing controlled substances must perform a “sufficient physical examination and take a medical history.” GX 32, at 8 (citing The Guide, at 57). With respect to S.M. and K.B., Registrant conducted minimal physical evaluations on the first visit and no physical evaluation on subsequent visits. See GX 31, at 2 (brief physical examination for S.M.); see also GX 5, at 11–12 (minimal physical evaluation of K.B.). Moreover, Registrant never conducted a physical examination on J.W. See GX 10, 14, 16. The video evidence demonstrates that Registrant spent most of the time during the appointments sitting behind his desk and writing prescriptions. See GX 1, GX 24. To the extent that Registrant conducted any physical evaluation on patients B.H. and M.C., it was not documented. See GX 21 and 22; see also GX 31, at 5. Dr. Munzing stated that the “Guide mandates that a physician should keep accurate and complete records.” GX 31, at 5 (citing to the Guide, at 59). Registrant also failed to complete any documented medical history, treatment plans other evaluations or consultations. See GX 31, at 5. Registrant failed to make any progress notes or treatment plans or even assessments of the patients’ pain. *Id.* He only maintained records of pain agreements for two out of the five individuals. *Id.* I find that Registrant failed to meet the standards for prescribing controlled substances in California as to B.H. and M.C.

Further, I find that Registrant ignored signs of abuse and/or diversion. I find that Registrant noticed drug-seeking behavior and failed to address that behavior as the applicable standard of care requires. Dr. Munzing credibly declared that: The 2014 Guidelines require that a physician prescribing controlled substances must “remain cognizant of aberrant or drug seeking behaviors”; the Physician’s Guide mandates that special attention be paid to patients who “pose a risk for medication misuse and/or diversion”; and, with limited exceptions, California state law forbids prescribing to an addict. GX 32, at 7, 8. S.M. asked for specific controlled substances and indicated that he was taking medication without a prescription. GX 31, at 2; GX 32, at 4. K.B. repeatedly requested increases in dosages, new medications, admitted to sharing her medication without a prescription and did very little to justify her need for the prescription. GX 7, at 4; GX 10, at 4, 17; GX 32, at 5, 6. J.W. admitted to

“dip[ping] into” her roommate’s controlled substances, and getting medication “off the street.” GX 10, at 17, 18. She asked for increased dosages and admitted to seeing another doctor for opioid prescriptions. GX 16, at 2, 3. B.H. and M.C. used multiple pharmacies, received high doses of dangerous prescription cocktails, and B.H. also used multiple addresses, and drove long distances. GX 32, at 11; *See e.g.*, GX 20, at 5, 6.

In sum, based on all of the evidence in the record, I find substantial evidence that Registrant prescribed controlled substances outside of the usual course of the professional practice in California and without a legitimate medical purpose.

#### *Allegations of Violations of State Law*

I also find that there is substantial evidence that Registrant violated state law. California law requires that a “prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.” Cal. Health & Safety Code § 11153(a) (Westlaw, current with urgency legislation through Ch 706 of the 2019 Regular Session). Further, a prescription is unlawful if it is issued to “an addict or habitual user” outside of a narcotic treatment program or professional practice. *Id.* Additionally, practitioners prescribing to addicts are required to comply with the regular practice of their profession and a patient receiving controlled substances must be under their “treatment for a pathology or condition.” *Id.* at 11154(a). With inapplicable exceptions to this situation, the state law again makes clear that “no person shall prescribe . . . a controlled substance . . . [for] an addict, or to any person representing himself or herself as such.” *Id.* at 11156(a). The California Business and Professions Code states that “prescribing . . . dangerous drugs . . . without an appropriate prior examination and a medical indication constitutes unprofessional conduct.” Cal. Bus. & Prof. Code § 2242(a) (Westlaw, current with urgency legislation through Ch 706 of the 2019 Regular Session). Additionally, California law states that “Repeated acts of clearly excessive prescribing, furnishing, dispensing, or administering of drugs or treatment . . . as determined by the standard of the community of licensees is unprofessional conduct for a physician.” Cal. Bus. & Prof. Code § 725(a) (Westlaw, current with urgency legislation through Ch 706 of the 2019 Regular Session).

I find that none of the controlled substances prescriptions issued to S.M., K.B., J.W. M.C., or B.H. were issued for a legitimate medical purpose. GX 32, at 11. Dr. Munzing opined, and I agree, that physical exams on S.M., K.B. and J.W. were either not conducted or were “wholly inadequate,” and that the three presented themselves as “drug seeking individuals and the amounts prescribed to them were both excessive and unjustified.” *Id.* at 8–10 (no evidence of a physical examination on M.C. or B.H.) Registrant ignored obvious signs of addiction to controlled substances and prescribed strong doses of controlled substances despite those signs. *Id.* at 11. Registrant’s failure to document or perform medical exams, and his repeated prescriptions below the standard of care constituted unprofessional conduct in California. *Id.* at 7.

#### *Allegation That Registrant Materially Falsified His Application for a COR*

The record evidence demonstrates that Registrant’s initial COR was suspended pursuant to an Order to Show Cause and Immediate Suspension Order, dated March 16, 2016, and that he surrendered this COR on March 18, 2016. GX 26, at 7; GX 17. The record also demonstrates that on May 20, 2016, Registrant completed an application for a new DEA COR. GX 18. Registrant answered in the negative to Question Number Two on the application, which reads “[h]as the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?” *Id.* at 1. Subsequently, on June 8, 2016, Registrant was issued a new registration. GX 25, at 1. When asked by the DI about the false statements on his application, Registrant stated that “he was trying to do what he thought was right for his patients.” GX 31, at 7. I find that the substantial evidence on the record shows that Registrant materially falsified his application for a COR.

#### **Discussion**

##### *Allegation That Registrant’s COR Is Inconsistent With the Public Interest*

Under Section 304 of the Controlled Substances Act (hereinafter, CSA), “[a] registration . . . to . . . 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 his registration under section 823 of this title inconsistent with the public interest as determined by such section.” 21 U.S.C.

824(a)(4). In the case of a “practitioner,” which is defined in 21 U.S.C. 802(21) to include a “physician,” 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 . . . controlled substances.
- (3) The applicant’s conviction record under Federal or State laws relating to the . . . 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. 21 U.S.C. 823(f). These factors are considered in the disjunctive. *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003).

According to Agency decisions, 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 revoke a COR. *Id.*; *see also Jones Total Health Care Pharmacy, LLC v. Drug Enf’t Admin.*, 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi v. Drug Enf’t Admin.*, 841 F.3d 707, 711 (6th Cir. 2016); *MacKay v. Drug Enf’t Admin.*, 664 F.3d 808, 816 (10th Cir. 2011); *Volkman v. U. S. Drug Enf’t Admin.*, 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie v. Drug Enf’t Admin.*, 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. “In short, . . . 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 misconduct.” *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a COR. *MacKay*, 664 F.3d at 821.

Under DEA’s regulation, “[a]ny hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied.” 21 CFR 1301.44(e). In this matter, while I have considered all of the factors, the Government’s evidence in support of its *prima facie* case is confined to Factors Two and

Four. I find that the Government's evidence with respect to Factors Two and Four satisfies its *prima facie* burden of showing that Registrant's continued registration would be "inconsistent with the public interest." 21 U.S.C. 823(f). However, Registrant's request for a hearing was untimely. I find that he had not rebutted the Government's *prima facie* showing. I find Registrant's misconduct to be egregious and I will order that Registrant's COR be revoked.

*Factors Two and/or Four—The Registrant's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances*

Under Factor Two, I evaluate the registrant's "experience in dispensing . . . with respect to controlled substances." 21 U.S.C. 823(f)(2). There is no evidence in the record as to the Registrant's positive dispensing experience; however, the Government has clearly established the Registrant's significant history of unlawful and dangerous dispensing practices through the undercover officer, confidential sources and the seized medical records.

Factor Four is demonstrated by evidence that a registrant has not complied with laws related to controlled substances, including violations of the CSA, DEA regulations, or other state or local laws regulating the dispensing of controlled substances. According to the CSA's implementing regulations, a lawful prescription for controlled substances is one that is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a). The Supreme Court has stated, in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, that "the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." *Gonzales v. Oregon, supra*, 546 U.S. at 274.

Under the CSA, it is fundamental that a practitioner must establish and maintain a legitimate doctor-patient relationship in order to act "in the usual course of . . . professional practice" and to issue a prescription for a "legitimate medical purpose." *Ralph J. Chambers*, 79 FR 4962 at 4970 (2014) (citing *Paul H. Volkman*, 73 FR 30629, 30642 (2008), *pet. for rev. denied Volkman v. Drug Enf't Admin.*, 567 F.3d 215, 223–24 (6th Cir. 2009)); see also

*U.S. v. Moore*, 423 U.S. 122, 142–43 (1975) (noting that evidence established that the physician exceeded the bounds of professional practice, when "he gave inadequate physical examinations or none at all," "ignored the results of the tests he did make," and "took no precautions against . . . misuse and diversion"). The CSA, however, generally looks to state law to determine whether a doctor and patient have established a legitimate doctor-patient relationship. *Volkman*, 73 FR 30642.

*Allegations that Registrant Prescribed Below the California Standard of Care*

In this case, as found above, Dr. Munzing has credibly opined that none of the prescriptions in evidence were issued for a legitimate medical purpose under the standard of care in California. GX 32, at 11. Registrant conducted little-to-no physical examination during all of the visits in violation of California law and below of the California standard of care. See *Moore*, 423 U.S. at 142–43 (noting that evidence established that physician "exceeded the bounds of professional practice," when, *inter alia*, "he gave inadequate physical examinations or none at all" and ignored signs of diversion); see also Cal. Bus. & Prof. Code section 2242(a) (requiring a "prior examination" before prescribing medication, such as controlled substances); see also *Gabriel Sanchez, M.D.*, 78 FR 59060, 59063–64 (2013) (finding that a doctor acted outside the usual course of professional practice by not conducting an adequate physical examination before prescribing controlled substances).

Additionally, as already discussed the evidence demonstrates that S.M., K.B. and J.W. were not seeking the drugs for a legitimate medical condition, but rather for the purpose of abusing or diverting them. See *e.g.*, GX 16, at 4 (When Registrant asked if the oxycodone controlled her pain, she said "it's good for sleeping."); see also GX 7, at 2 (K.B. wanted to try Adderall because the oxycodone made her tired); see also GX 10, at 35 (J.W. asked for Adderall "for studying"). These prescriptions amounted to "outright drug deals." *James Clopton, M.D.*, 79 FR 2475, 2478 (2014) (holding that a California physician who prescribed controlled substances to an undercover with no physical exam after the undercover disclosed that he borrowed pills from a friend and that the medication's purpose was "it helps [me] unwind" to be a clear violation of the law amounting to a drug deal). I also find that Registrant, by his own repeated admissions, demonstrated that the purpose of any constraint he was

exercising in his prescribing practices was to avoid detection. See *e.g.*, GX 8, at 14 (Registrant told J.W. that when first prescribing it looked "bad to like hit them with the highest dosage," and then increased the dosage on the second visit when requested). I further find that Registrant blatantly altered his rationale for his prescribing pain medication for J.W. from her ankle to her neck on the prescription stating that her "neck injury here—it's just—it's more of a potentially serious injury." GX 10, at 39. Based on this and all of the other evidence herein, I find that Registrant prescribed below the standard of care in California and issued prescriptions without a legitimate medical purpose.

*Allegations of Violations of State and Federal Law*

OSCs 1 and 2 alleged multiple violations of state law and unprofessional conduct in violation of California Health and Safety Code §§ 11153(a), 11154(a), 11156 and California Business Professional Code §§ 725, 2242(a).<sup>39</sup> In addition, the OSCs alleged the Registrant's issuance of prescriptions for controlled substances without a medical purpose violated 21 U.S.C. 841(a)(1) (unlawful distribution of a controlled substance) and 21 CFR 1306.04(a) ("A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice"). I find that the Government has established that the controlled substances were prescribed without a legitimate medical purpose and below the standard of care in California, and in violation of state law, as detailed above, and therefore that Registrant's prescribing practices violated federal law.

*Summary of Factors Two and Four and Imminent Danger*

As found above, the Government's case establishes by substantial evidence that Registrant issued controlled substance prescriptions outside the usual course of the professional practice. I conclude that Registrant engaged in egregious misconduct, which supports the revocation of his COR. See *Wesley Pope*, 82 FR 14944, 14985 (2017).

For purposes of the imminent danger inquiry, my findings also lead to the conclusion that Registrant has "fail[ed] . . . to maintain effective controls

<sup>39</sup>I am excluding Cal. Bus. & Prof. Code section 2234 from my finding regarding violations of state law, because neither the Government's Expert, nor the Government fully explained its application to this proceeding.

against diversion or otherwise comply with the obligations of a registrant” under the CSA. 21 U.S.C. 824(d)(2). Dr. Munzing credibly opined that Registrant’s “treatment of M.C. and B.H. was both dangerous and reckless and fell far below the standard of care for prescribing controlled substances in the State of California,” and stated that he was “particularly concerned that [Registrant] was continuing to prescribe excessive amounts of opioid medication and prescription cocktails to both M.C. and B.H., even after he had surrendered one DEA registration . . . and obtained another. . . .” GX 32, at 10. The substantial evidence that Registrant issued controlled substance prescriptions outside the usual course of the professional practice 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’s registration. *Id.* Therefore, I affirm the ISO<sup>40</sup> issued on Registrant’s COR.

#### Allegation That Registrant Materially Falsified His Application for a COR

Based on the facts of this case, it is abundantly clear that Registrant falsified his application in answering in the negative to the question about surrendering his COR. GX 18, at 1. The Government argues that Registrant’s negative answer meets the test of “misrepresentation or concealment . . . predictably capable of affecting the official decision” and thus “meets the definition of materiality.” RFAA, at 21, citing *Scott C. Bickman, M.D.*, 76 FR 17694, 17701 (2011), quoting *Kungys v. United States*, 485 U.S. 759, 770, (1988). The Government contends that Registrant’s “subsequent DEA registration would not have been granted” had Registrant disclosed OSC 1 at the time of the application. RFAA, at 21.

I find that Registrant’s answer of “N” [symbolizing “no”] to the question of whether he had surrendered his COR was materially false.

Registrant’s false answer clearly affected the decision of whether to grant his application. See *Jose G. Zavaleta, M.D.* 78 FR 27431 (2013) (physician’s failure to disclose prior voluntary surrender of DEA COR following investigation into prescribing to

undercover officers was clearly capable of influencing the decision of the Agency and thus material); see also *Arthur H. Bell, D.O.*, 80 FR 50033, at 50038 (2015).

I therefore find substantial evidence that Registrant materially falsified his May 20, 2016, application for registration when he failed to disclose that he had surrendered his DEA registration “for cause.” I further conclude that this finding alone constitutes an independent basis for revocation of Registrant’s COR. See *Murphy v. Drug Enf’t Admin.* 111 F.3d 140 (10th Cir. 1997) (finding that “material falsification of his application is itself sufficient grounds for revocation of his COR.”)

In sum, I find that there is substantial evidence on the record that Registrant repeatedly issued prescriptions for controlled substances without a legitimate medical purpose and dangerously below the standard of care in California, committed multiple violations of state law, and engaged in numerous acts of unprofessional conduct in violation of state law. Further, I find that Registrant materially falsified his application for a DEA COR after having been served with OSC 1 and surrendering his previous COR, which constitutes an independent basis for revocation of Registrant’s COR.

#### Sanction

Where, as here, the Government has met its *prima facie* burden of showing by two independent bases that Registrant’s COR should be revoked because he materially falsified his application and his continued registration is inconsistent with the public interest, the burden shifts to the Registrant to show why he can be entrusted with a registration. *Garrett Howard Smith, M.D.*, 83 FR 18882, 18910 (2018) (collecting cases).

The CSA authorizes the Attorney General to “promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.” 21 U.S.C. 871(b). This authority specifically relates “to ‘registration’ and ‘control,’ and ‘for the efficient execution of his functions’ under the statute.” *Gonzales*, 546 U.S. at 259. “Because ‘past performance is the best predictor of future performance,’ *ALRA Labs, Inc. v. Drug Enf’t Admin.*, 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the

registrant’s] actions and demonstrate that [registrant] will not engage in future misconduct.” *Jayam Krishna-Iyer*, 74 FR at 463 (quoting *Medicine Shoppe*, 73 FR 364, 387 (2008)); see also *Jackson*, 72 FR at 23853; *John H. Kennedey, M.D.*, 71 FR 35705, 35709 (2006); *Prince George Daniels, D.D.S.*, 60 FR 62884, 62887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant; therefore, the Agency looks at factors, such as the acceptance of responsibility, and the credibility of that acceptance as it relates to the probability of repeat violations or behavior, and the nature of the misconduct that forms the basis for sanction, while also considering the Agency’s interest in deterring similar acts. See *Arvinder Singh, M.D.*, 81 FR 8247, 8248 (2016).

Here, Registrant failed to timely respond to the Government’s second Order to Show Cause and Immediate Suspension Order and did not avail himself of the opportunity to refute the Government’s case. As such, Registrant has made no representations as to his future compliance with the CSA or to demonstrate that he can be entrusted with a COR. All evidence of Registrant’s egregious conduct constituting two independent bases for revocation indicates clearly that he cannot be so entrusted.

Accordingly, I shall order the sanctions the Government requested, as contained in the Order below.

#### Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f) and 824(a), I hereby revoke DEA Certificate of Registration FO6043638 issued to Jeffrey Olsen, M.D. I further hereby deny any pending application of Jeffrey D. Olsen, M.D., to renew or modify this COR, as well as any other applications of Jeffrey D. Olsen, M.D. for an additional COR in California. Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and (d), I hereby affirm the Order of Immediate Suspension of Registration issued to Jeffrey Olsen, M.D. This Order is effective January 15, 2020.

Dated: December 6, 2019.

**Uttam Dhillon,**

*Acting Administrator.*

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**BILLING CODE 4410–09–P**

<sup>40</sup> As explained herein, OSC/ISO 2 incorporated by reference OSC/ISO 1, and therefore, I am issuing this revocation on the bases of both OSC/ISOs issued on Registrant’s COR, and in affirming OSC/ISO 2, I am also affirming OSC/ISO 1. See OSC 2, at 2.