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OPINION OF THE SECOND CIRCUIT (AUGUST 29, 2018)

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

UNITED STATES,

v.

AHUJA.

No. 17-2098-cv

We review a district court's award of civil penalties for abuse of discretion. *Advance Pharm., Inc. v. United States*, 391 F.3d 377, 398 (2d Cir. 2004). "A court abuses its discretion 'when (1) its decision rests on an error of law (such as application of the wrong legal principle) or a clearly erroneous factual finding, or (2) its decision-though not necessarily the product of a legal error or a clearly erroneous factual finding-cannot be located within the range of permissible decisions.'" *Slupinski v. First Unum Life Ins. Co.*, 554 F.3d 38, 47 (2d Cir. 2009) (quoting *Zervos v. Verizon New York, Inc.*, 252 F.3d 163, 169 (2d Cir. 2001) (footnote omitted)).

The district court did not abuse its discretion by ordering Ahuja's fine. When determining a civil penalty for violations of the CSA, the district court should consider: "(1) the level of defendant's culpability, (2) the public harm caused by the violations, (3) defendant's profits from the violations, and (4) defendant's ability to pay a penalty." *Advance Pharm., Inc.*, 391

F.3d at 399. Ahuja challenges the district court's findings in three of these categories.

A. Culpability

A district court should consider the totality of the evidence when determining a defendant's culpability, including the "good or bad faith" conduct of a defendant. *Id.* Here, the district court's conclusion that Ahuja was grossly negligent and therefore highly culpable is supported by the record. Ahuja admitted committing over 1,000 violations of the CSA in three years. These consisted of a complete failure to keep adequate records, conduct inventory, and maintain the security of the controlled substances in his medical clinic.[1] Although Ahuja kept some records, he admitted that the records were ineffective as they did not enable him to keep track of the drugs. Further, Ahuja could not account for 100 percent of his shipments for four different drugs. Ahuja asserts that he did not act willfully or intentionally and therefore was not highly culpable. But evidence of willfulness is not required by *Advance Pharmaceutical* to merit imposition of a high penalty. Rather, the district court is called upon to assess the totality of the evidence to determine the defendant's culpability. *See id.*

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[1] Ahuja does not challenge the district court's calculation of the total number of individual violations. Rather, as discussed below, he challenges only the imposition of a $10,000 fine per violation. Because he does not argue that the district court's counting methodology was wrong, he has waived that issue. *See LoSacco v. City of Middletown*, 71 F.3d 88, 92-93 (2d Cir. 1995). We therefore use the district court's calculation of the total number of violations.

B. Public Harm

A court must also consider the public harm caused by the defendant's actions, such as evidence that drugs have actually been used illegally. *Id.*; *see also United States v. Glob. Distribs., Inc.*, 498 F.3d 613, 620-21 (7th Cir. 2007) (conversion of drugs into a large amount of methamphetamine "cuts in favor of a stiff penalty"). Other considerations include the risk of side effects from the controlled substances and whether a defendant's violation made it impossible to tell if any drugs were diverted. Here, the evidence supports the district court's conclusion that Ahuja warranted a higher fine. Ahuja could not account for approximately $28,000 worth of controlled substances, which included over 5,000 pills and a significant percentage of the total amount of the drugs he received. His failure to keep proper records created a risk that patients could abuse their prescriptions and, in fact, did so; the impetus for the investigation was that one of Ahuja's patients had been "sharing" his alprazolam pills. Ahuja's lack of physical security for the drugs meant that unauthorized persons could easily access them, a conclusion supported by Ahuja's own theory that a secretary stole the drugs.

C. Ability to Pay

A district court must also examine evidence of the defendant's financial condition and determine if he has the ability to pay. *Advance Pharm., Inc.*, 391 F.3d at 399-400. The district court's finding that Ahuja could pay a fine was supported by the record. Ahuja's salary ranged from approximately $150,000 to $200,000 per year. Although Ahuja argued that the lower figure was more accurate, he offered conflicting explanations for his higher 2014 income. Further,

Ahuja owned stocks, but he failed to offer any evidence about the value of those stocks. Although Ahuja stated he suffered from health problems that would affect his ability to work, he did not offer any medical evidence about those problems. Ahuja argues that the district court erred by requiring him to prove his inability to pay a fine rather than requiring the Government to show that he could pay a fine. But Ahuja bore the burden of showing that he could not pay the fine. *See Motorola Credit Corp. v. Uzan*, 509 F.3d 74, 84-85 (2d Cir. 2007) (affirming civil fine imposed in part because the defendant had not shown an inability to pay).

We have considered all of Ahuja's remaining arguments and find them to be without merit. For the reasons stated, the judgment of the district court is AFFIRMED.

OPINION OF THE DISTRICT COURT OF CONNECTICUT (MAY 5, 2017)

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

UNITED STATES,

v.

AHUJA.

Civil Action No. 3:14-CV-1558 (JCH)
Before: Janet C. HALL, U.S District Judge

RULING ON PENALTIES

I. Introduction

On November 22, 2016, Dr. Ajay S. Ahuja, M.D. ("Dr. Ahuja"), the defendant, admitted liability for twenty-three counts of civil violations of the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 et. seq.[1] *See* Minute Entry (Doc. No. 126) ("Dr. Ahuja admitted each of Counts 1-23."); Am. Compl. (Doc. No. 106) (alleging twenty-three CSA violations). The plaintiff, the United States ("the Government"), asks the court to assess civil penalties against Dr. Ahuja of $496,500,[2] *see*

[1] Because Dr. Ahuja admitted these violations, jury selection was cancelled.

[2] The Government first suggested this $496,500 figure in the context of its Motion for Default Judgment (Doc. No. 14). *See* Mot. for Default ¶ 10. The Government explained therein that the $496,500 figure was based on requesting the court impose $500 per violation for each of the 961 violations that carry a

March 7, 2017 Hearing Transcript ("Tr.") (Doc. No. 153) at 143, and asks the court to order Dr. Ahuja "to comply with all federal laws and regulations pertaining to receipts, dispensations, and inventories of controlled substances" in the future, Am. Compl. at 8. Dr. Ahuja argues that the amount of penalties should be $28,462.16. *See* Tr. at 155.

The court accepted written affidavits in lieu of direct testimony and held an evidentiary hearing to hear cross-examination in order to then determine the amount of penalties.[3]

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maximum penalty of $10,000, and $1,000 per violation for each of the sixteen violations that carry a maximum penalty of $25,000. *See id.* ¶ 10. The court explains the number of violations and maximum penalties below. *See infra* Section V(A)(1) (explaining that Counts One through Eighteen constitute 961 violations, each of which carry a maximum penalty of $10,000); V(A)(2) (explaining that Counts Nineteen through Twenty-Three constitute sixteen violations, each of which carry a maximum penalty of $25,000).

[3] While a jury would typically determine liability for a civil CSA violation, once liability has been decided, the court itself may determine the penalty amount. *See, e.g.*, *Advance Pharmaceutical v. United States*, 391 F.3d 377, 389 (2d Cir. 2004) (describing case in which, after jury found liability, court held hearing to determine penalty); *United States v. Bizga*, No. 1:13-CV-206, 2014 U.S. Dist. LEXIS 185900, 2014 WL 11370407, at *1 (N.D. Ohio Apr. 8, 2014) ("The parties stipulated to [the defendant]'s liability for violations of the CSA and accompanying regulations, and agreed that the Court would determine the civil penalties to be assessed, if any, following a hearing."); *United States v. Paskon*, No. 4:07-CV-1161 (CEJ), 2008 U.S. Dist. LEXIS 91045, 2008 WL 4948458, at *1 (E.D. Mo. Nov. 10, 2008) ("This matter is before the Court for determination of damages, penalties, and injunctive relief following the jury's verdict on the claims brought by the United States pursuant to . . . the Controlled Substances Act."); *United States v. Salcedo*, No. 02-CV-1095 (FB) (VVP), 2003 U.S. Dist. LEXIS

For the reasons that follow, the court ORDERS Dr. Ahuja to pay $200,000 and to comply with all federal laws and regulations pertaining to receipts, dispensations, and inventories of controlled substances in the future.

II. Admitted Violations

Dr. Ahuja is a practitioner registered with the Drug Enforcement Administration and authorized to handle controlled substances. *See* Am. Compl. at 1. The counts, all of which Dr. Ahuja admits, set forth the following violations:

Counts One through Eight set forth violations of section 842(a)(5) of title 21 of the United States Code[4] and section 1304.04(a) of title 21 of the Code of Federal Regulations,[5] based on failure to maintain controlled substance receipt records for (1) seventeen shipments of Alprazolam, *see* Am. Compl. Count I, (2) eight shipments of Hydrocodone Bitartrate with Acetaminophen, *see id.* Count II, (3) seven shipments of Guaifenesin with Codeine Phosphate, *see id.* Count III, (4) one shipment of Testosterone Cypionate, *see id.* Count IV, (5) one shipment of Zolpidem Tartrate, *see id.* Count V, (6) ten shipments of 75-milligram

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8561, 2003 WL 21196843, at *1 (E.D.N.Y. Feb. 19, 2003) (stating that, after "default judgment against defendant," court referred matter to magistrate "for determination of the relief to be granted plaintiff"). The parties agreed that the amount of the penalty is for the court to determine.

[4] Section 842(a)(5) makes it unlawful "to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under" the CSA. 21 U.S.C. § 842(a)(5).

[5] Section 1304.04(a) requires the keeping of certain records. *See* 21 C.F.R. § 1304.04(a).

Lyrica tablets, *see id.* Count VI, (7) eight shipments of 50-milligram Lyrica tablets, *see id.* Count VII, and (8) one partially-used vial of Depo-Testosterone, *see id.* Count VIII.

Count Nine sets forth a violation of section 1304.04(f)(2) of title 21 of the Code of Federal Regulations[6] for failure to separate controlled substance records for Schedule III, IV, and V substances from records for non-controlled substances. *See* Am. Compl. Count IX.

Count Ten sets forth a violation of section 827(a)(1) of title 21 of the United States Code[7] and section 1304.11(c) of title 21 of the Code of Federal Regulations[8] based on failure "to perform and maintain a biennial inventory of controlled substances." Am. Compl. Count X.

Counts Eleven and Twelve set forth violations of section 827(a)(3) of title 21 of the United States Code,[9] and either section 1304.21(a)[10] or 1304.22(c)[11]

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[6] Section 1304.04(f)(2) states that "[i]nventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant." 21 C.F.R. § 1304.04(f)(2).

[7] Section 827(a)(1) requires a "complete and accurate record of all stocks [of controlled substances] on hand." 21 U.S.C. § 827(a)(1).

[8] Section 1304.11(c) requires a "biennial inventory." 21 C.F.R. § 1304.11(c).

[9] Section 827(a)(3) requires "a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of." 21 U.S.C. § 827(a)(3).

[10] Section 1304.21(a) requires "a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of." 21 C.F.R. § 1304.21(a).

of title 21 of the Code of Federal Regulations, for failures (11) "to maintain accurate dispensing records for" Alprazolam, resulting in failure to account for 59 bottles, Am. Compl. Count XI, and (12) to properly complete a dispensation log for 517 bottles of this drug, *see id.* Count XII.

Counts Thirteen and Fourteen set forth violations of section 827(a)(3), and either section 1304.21(a) or 1304.22(c), for failures (13) "to maintain accurate dispensing records for" Hydrocodone Bitartrate with Acetaminophen, resulting in failure to account for 21 bottles, Am. Compl. Count XIII, and (14) to properly complete a dispensation log for 92 bottles of this drug, *see id.* Count XIV.

Counts Fifteen and Sixteen set forth violations of section 827(a)(3), and either section 1304.21(a) or 1304.22(c), for failures (15) "to maintain accurate dispensing records for" Guaifenesin with Codeine Phosphate, resulting in failure to account for 58 bottles, Am. Compl. Count XV and (16) to properly complete dispensation logs for 154 bottles of this drug, *see id.* Count XVI.

Counts Seventeen and Eighteen set forth violations of section 827(a)(3) and section 1304.21(a) for failure "to maintain accurate dispensing records for" (17) Testosterone Cypionate, resulting in failure to account for two vials, Am. Compl. Count XVII, and (18)

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11 Section 1304.22(c) requires records "of the number of units or volume of [controlled substances in] finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser." 21 C.F.R. 1304.22(c).

Zolpidem Tartrate, resulting in failure to account for three bottles, *id.* Count XVIII.

Counts Nineteen and Twenty set forth violations of sections 842(a)(1)[12] and 842(c)(1)(A)[13] of title 21 of the United States Code, and section 1306.04(a) of title 21 of the Code of Federal Regulations,[14] for dispensing "controlled substances outside of the usual course of [Dr. Ahuja's] professional practice," namely, (19) to Dr. Ahuja's ex-wife, Gurpreet Ahuja ("Gurpreet"), either Hydrocodone with Acetaminophen, or Alprazolam, on a total of four different occasions, Am. Compl. Count XIX; *see also* Dr. Ahuja Aff. (Def. Ex. A) ¶ 7(l) (clarifying that "Jane Doe #1," referred to in this Count, is Gurpreet), and (20) to his son,

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12 Section 842(a)(1) makes it unlawful for a registrant "to distribute or dispense a controlled substance in violation of section 829 of [ ] title [21 of the United States Code]." 21 U.S.C. § 842(a)(1).

While the Amended Complaint incorrectly lists section 842(a)(2) in these counts, the Government clarified via email to the court on March 3rd, 2017, with copy to defense counsel, that the Government meant to list section 842(a)(1).

13 Section 842(c)(1)(A) states that "any person who violates" section 842(a)(1), "shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000." 21 U.S.C. § 842(c)(1)(A).

While the Amended Complaint incorrectly lists section 841(a)(1) in these counts, the Government clarified in the same email that the Government meant to list section 842(c)(1)(A).

14 Section 1306.04(a) requires that "[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." 21 C.F.R. 1306.04(a).

While the Amended Complaint incorrectly lists section 1306.21(b) in these counts, the Government clarified via email to the court that the Government meant to list section 1306.04(a).

Sunny Ahuja, Guaifenesin with Codeine, on two different occasions, *id.* Count XX; *see also* Sunny Ahuja ("Sunny") Aff. (Def. Ex. C) ¶ 5 (clarifying that "John Doe #1," referred to in this Count, is Sunny).

Counts Twenty-One and Twenty-Two set forth violations of sections 842(a)(1) and 842(c)(1)(A),[15] and section 1306.04(a) of title 21 of the Code of Federal Regulations, for prescribing "controlled substances outside of the usual course of [Dr. Ahuja's] professional practice," namely, (21) to his son, Nicholas Ahuja ("Nicholas"), Zolpidem, on five different occasions, Am. Compl. Count XXI; *see also* Nicholas Aff. (Def. Ex. B) ¶ 5 (clarifying that "John Doe #2" listed in this Count is Nicholas), and (22) to his brother, Uttam Ahuja ("Uttam"), either Cheratussin AC, Hydrocodone Bitartrate, or Hydrocodone Chlorpheniramine, on a total of three different occasions, *id.* Count XXII; *see also* Uttam Aff. (Def. Ex. D) ¶ 5 (clarifying that "John Doe #3" listed in this Count is Uttam).

Count Twenty-Three sets forth violations of section 842(a)(1) and 842(c)(1)(A) of title 21 of the United States Code[16] for illegal possession of two (full or partial) bottles of Alprazolam which had previously been dispensed to Nicholas or Uttam. *See* Am. Compl. Count XXIII.

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15 Again, while the Amended Complaint incorrectly lists sections 841(a)(1) and 842(a)(2) in these counts, the Government clarified via email to the court that the Government meant to list sections 842(a)(1) and 842(c)(1)(A).

16 While the Amended Complaint incorrectly lists section 841(a)(1) in Count Twenty-Three, the Government clarified during the hearing that the Government meant to list section 842(a)(1) and 842(c)(1)(A) here, as well. *See* Tr. at 3.

III. Legal Standard

Maximum penalties for the various violations of law by Dr. Ahuja are set out in the statutes. "[A]ny person who violates" section 842(a)(1), "shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000." 21 U.S.C. § 842(c)(1)(A). "In the case of a violation of" section 842(a)(5), "the civil penalty shall not exceed $10,000." 21 U.S.C. § 842(c)(1)(B).

The parties agree that the Second Circuit's decision in Advance Pharmaceutical, Inc. v. United States, 391 F.3d 377 (2d Cir. 2004), provides the standard for determining the size of a reasonable penalty. *See* Pl.'s Mem. (Doc. No. 134) at 1; Def.'s Mem. (Doc. No. 135) at 1. According to *Advance Pharmaceutical*,

> a district court may properly consider a number of factors in determining the size of a civil penalty, including the good or bad faith of the defendants, the injury to the public, and the defendant['s] ability to pay. Thus, in determining monetary penalties under § 842 (c), district courts have frequently considered four factors: (1) the level of defendant's culpability, (2) the public harm caused by the violations, (3) defendant's profits from the violations, and (4) defendant's ability to pay a penalty.

391 F.3d at 399 (internal quotation marks and citation omitted); Pl.'s Mem. at 1-2; Def.'s Mem. at 1-2.

IV. Findings of Fact

A. Culpability

The court finds that Dr. Ahuja engaged in the following conduct, or lack of conduct: (1) Dr. Ahuja

dispensed controlled substances directly from his practice, despite the fact that most physicians choose instead to only "write prescriptions" and have "pharmacies dispense the medicines," *see, e.g.*, Marcie L. Johnson ("Johnson") Aff. (Gov. Ex. 39) ¶ 14, (2) Dr. Ahuja prescribed controlled substances to family members, *see, e.g.*, *id.* ¶ 11; Dr. Ahuja Aff. ¶ 7(l), (3) Dr. Ahuja failed to make proper notations in family members' patient charts when prescribing controlled substances to them, *see, e.g.*, Tr. at 61-62, (4) Dr. Ahuja failed to properly record dispensations in his dispensation log, *see* Dr. Ahuja Aff. ¶ 7(e),(g),(i), (5) Dr. Ahuja failed to conduct a biennial inventory of the controlled substances he had on hand, for three to four years in a row, *see* Am. Compl. Count X; Johnson Aff. ¶ 28; Dr. Ahuja Aff. ¶ 7(d); Tr. at 112; and, as a result of this failure to conduct a biennial inventory, Dr. Ahuja lacked a method of noting whether controlled substances had gone missing, *see* Tr. at 112, (6) Dr. Ahuja cannot account for certain medications, *see, e.g.*, Dr. Ahuja Aff. ¶ 7(d),(f),(h),(j),(m),(k), (7) Dr. Ahuja consistently failed to upload information to the Connecticut Prescription Monitoring and Reporting System (CPMRS) regarding his dispensations of controlled substances to patients, thus preventing other doctors from knowing whether their patients may have been receiving controlled substances from more than one source, *see* Rodrick J. Marriott ("Marriott") Aff. (Gov. Ex. 37) ¶ 8; Tr. at 103, and, (8) if Dr. Ahuja's own theory were to be credited (which it is not),[17]

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[17] Dr. Ahuja's testimony and demeanor at the evidentiary hearing leads the court to discredit most of his testimony. For instance, while Dr. Ahuja had admitted liability on all counts of the Amended Complaint at a prior court proceeding, Dr. Ahuja stated during the evidentiary hearing that he had only admitted liability to

due to his insufficient security measures and failure to properly keep track of his medication, Dr. Ahuja allowed controlled substances to be stolen by his former secretary, who presumably used the substances for an illicit purpose; and Dr. Ahuja then failed to report this diversion to law enforcement officials, *see* Tr. at 95-96, 110-12, 115-16, 121-23.

The court credits and agrees with the opinion of University of Connecticut School of Medicine Assistant Clinical Professor in Family Medicine, Dr. Adam Perrin, M.D. ("Dr. Perrin"), that Dr. Ahuja's behavior reflects "a blatant disregard for the rigor and careful oversight required for the safe and proper dispensing and prescribing of controlled substances." Dr. Perrin Expert Report at 8. While Dr. Ahuja testified that he "was making an attempt to keep the required records," Dr. Ahuja Aff. ¶ 7, the court views those efforts as essentially non-existent.

B. Public Harm

The court finds that, with regard to Dr. Ahuja's family members who were given controlled substances, (1) the medications were given to treat bona fide

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"most" of the Amended Complaint, and did not admit liability on every count. *See* Tr. at 88-89. Dr. Ahuja later acknowledged that he had in fact admitted liability to the entire Amended Complaint. *See id.* at 90-91. He then stated that he wished to withdraw a portion of his admission of liability. *See id.* at 113. During this same March 7, 2017 evidentiary hearing, and in connection with changing his mind about the extent of his prior admission of liability, Dr. Ahuja renounced a portion of the Affidavit that Dr. Ahuja had signed only six days previously—on March 1st, 2017. *See id.* at 89-90, 113. Dr. Ahuja had sworn to the accuracy of his Affidavit at the evidentiary hearing, only moments before renouncing a portion of it. *See id.* at 85. During the hearing, Dr. Ahuja gave several other contradictory answers as well.

illnesses, (2) Dr. Ahuja checked up with them regarding the medications and the illnesses, and (3) the medications were effective. *See* Nicholas Aff. ¶ 5, Sunny Ahuja Aff. ¶ 5, Uttam Aff. ¶ 6.

However, the court finds that approximately $28,500 worth of drugs were diverted for non-medical purposes due to Dr. Ahuja's violations. Dr. Ahuja—in an apparent attempt to buttress his argument that he had not taken drugs from his own supply—presented a theory that his former secretary had stolen the missing medications from him, under circumstances that lead to the conclusion that the secretary would have used or sold the drugs for non-medical purposes. *See* Tr. at 95-96; *see also* Tr. at 111 (clarifying that Dr. Ahuja believes the secretary took all his missing medication). According to DEA Diversion Group Supervisor Leonard Levin ("Levin"), the total street value for all the unaccounted-for medications is $28,462.18. *See* Levin Aff. ¶ 27. The court notes that, if Dr. Ahuja invented his theory about the secretary stealing his drugs to deflect attention from his own malfeasance, the court can only assume that the truth is something worse than the secretary stealing the drugs—such as Dr. Ahuja directly diverting this $28,500 worth of controlled substances by consuming them himself or distributing them for non-medical purposes at a price of $4 per Alprazolam pill, $7 per Hydrocodone pill, $13.50 per bottle of Guaifenesin with Codeine, $84.89 per vial of Testosterone Cypionate, and $20.67 per bottle of Zolpidem tartrate. *See id.* ¶¶ 25-26.

The court finds, as Johnson testified, that "[t]he failure to report" the dispensation of controlled substances,

> allows for the diversion of controlled substances. Specifically, the patient can be seeing another provider and the other provider would have no way of knowing that the patient is also receiving controlled substances from Dr. Ahuja. This exposes the patient and, if the patient is not personally using the controlled substances, the community, to harm.

Johnson Aff. ¶ 63. The court further finds, based on Dr. Perrin's testimony, that, for a practitioner to have "controlled substances on site" involves an "inherent risk of theft and misuse," which "calls for strict policy and procedure in establishing a protocol to insure security, proper handling and appropriate dispensing practices." Dr. Perrin Expert Report at 8. By failing to exercise proper vigilance, the court finds that Dr. Ahuja created a volatile situation that put his patients and family members at risk of harm from improper use of addictive substances. *Id.* at 8; *see also* Dr. Ahuja Aff. ¶ 11 (stating that Dr. Ahuja does "not dispute that wide-spread abuse of controlled substances has reached crisis levels in the United States at this time").

C. Profit

The court finds that Dr. Ahuja can be expected to have made a profit of approximately $3,000 from his CSA violations. As detailed below, this profit estimation is based on the estimated retail value of the unaccounted-for drugs, subtracting the estimated cost Dr. Ahuja paid to buy these drugs. In making a profit finding, the court was required to decide between counting either (1) the retail value of the missing drugs, or (2) their street value. In deciding to use the retail value, the court does not simply rely on Dr.

Ahuja's testimony that he sold the drugs at their retail value, *see* Dr. Ahuja Aff. ¶ 10, because the court does not find Dr. Ahuja to be credible. However, the Government has presented no evidence that Dr. Ahuja operated his medical office as a "pill factory" or "pill mill," meaning an illegal prescription drug dealing business disguised as a medical office, that exists solely to distribute controlled substances. *See, e.g., United States v. Duprey*, 652 F. App'x 107, 108-09 (3d Cir. 2016) (describing as "pill factory" doctor's office where numerous pseudo-patients received weekly, highly uniform, controlled substance prescriptions, for the purpose of giving their pills to the doctor's co-conspirator; and affirming conviction of co-conspirator, who drove pseudo-patients to the doctor's office and to the pharmacist—another co-conspirator—before collecting pills from pseudo-patients and reselling them); *United States v. Guzman*, 571 F. App'x 356, 357-58, 360 (6th Cir. 2014) (agreeing that use of term "pill mill" accurately described allegations, and affirming conviction, where defendant ran a purported pain management clinic, which "bore all the hallmarks of an illegal operation," such as an unusually high amount of customer traffic—including customers from several other states, and customers who arrived in large groups all to receive the same type of prescription—, drug deals occurring in the parking lot, customers lingering in cars outside the clinic in a semi-conscious state, people "sponsor[ing]" customers to buy drugs for them, "skyrocket[ting]" prescription drug use in the county after the business opened, an emphasis on speed rather than careful patient examinations, a refusal to accept insurance coupled with an unusually large amount of business done in cash, the fact that patients generally had no obvious

symptoms, and the fact that patients often requested specific forms of drugs—such as drugs with particular markings). The Government has not argued that Dr. Ahuja's medical office was run as a pill factory or pill mill, and it has presented no evidence from which the court could infer that Dr. Ahuja's business was run in this way. For instance, the Government has presented no evidence (1) that every patient received controlled substances, rather than at least some patients receiving medical care that did not involve controlled substances, (2) that patients resold their drugs, (3) that the clinic had an unusually high number of patients, or attracted patients in large groups, or from surprisingly far away, (4) that the clinic failed to properly examine patients, or (5) that the patients lacked legitimate medical needs. In the absence of such evidence, the court concludes that it would be speculative to assume that Dr. Ahuja ran his business as a pill factory. Because the Government bears the burden of proof, *see, e.g.*, *Advance Pharmaceutical*, 391 F.3d at 391, the court defaults to the assumption that Dr. Ahuja ran his business as a legitimate medical operation, and thus that he sold medications at their retail value, rather than at their street value.[18]

Dr. Ahuja claims that any profits he "obtained through the dispensing of controlled substances have been negligible." Dr. Ahuja Aff. ¶ 10. Dr. Ahuja asserts that he generally dispensed each 90-milligram bottle

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[18] The court emphasizes that this conclusion does not excuse the egregiousness of Dr. Ahuja's reckless failure to take precautions to protect against the dangers of prescription drugs.

And Dr. Ahuja's failure to keep records impeded the Government's ability to determine how much profit Dr. Ahuja made from unlawfully dispensing controlled substances.

of Alprazolam for $30, which he says is the retail value. *See* Dr. Ahuja Aff. ¶ 10. Based on Dr. Ahuja's numbers, the cost to a patient for one pill of Alprazolam is $0.33. The Government has not presented alternative evidence of the retail value of Alprazolam. *See* Levin Aff. ¶¶ 25-26. However, Levin calculates that the street value of one pill is approximately $4. *See id.* ¶ 25. A large discrepancy exists between Dr. Ahuja's description of the retail value, and Levin's description of the street value. As discussed above, because the Government bears the burden of proof, and because there is no evidence that Dr. Ahuja, if he sold the missing medications, sold them for the higher street value, rather than the lower retail value, the court considers the retail value to be the relevant price. Dr. Ahuja states that each bottle of Alprazolam cost him approximately $10. *See* Dr. Ahuja Aff. ¶ 10. The Government has not offered any evidence to the contrary. *See* Levin Aff. ¶ 25. Based on Dr. Ahuja's figures, he thus generally made a profit of approximately $20 per bottle. In the absence of contrary evidence regarding the retail value of Alprazolam or the price Dr. Ahuja paid for Alprazolam, the court finds that Dr. Ahuja made a profit of approximately $20 per bottle of Alprazolam sold. Dr. Ahuja failed to account for 59 bottles of Alprazolam. *See* Am. Compl. Count XI. Dr. Ahuja thus would have made a profit of approximately $1,180 by dispensing the unaccounted-for Alprazolam.

Dr. Ahuja states that he dispensed a 30-tablet bottle of Hydrocodone for approximately $30, which he says is the retail value. *See* Dr. Ahuja Aff. ¶ 10. The court again considers the retail value to be the relevant consideration. Again, the Government has not presented any contrary evidence as to the retail

value of Hydrocodone. *See* Levin Aff. ¶¶ 25-26. Dr. Ahuja states that each bottle cost him approximately $10, thus indicating that he generally made a profit of approximately $20 per bottle. *See* Dr. Ahuja Aff. ¶ 10. The Government has not presented any evidence to the contrary. *See* Levin Aff. ¶ 25. Dr. Ahuja failed to account for 21 bottles of Hydrocodone. *See* Am. Compl. Count XIII. Dr. Ahuja thus would have made a profit of approximately $420 by dispensing the unaccounted-for Hydrocodone.

Dr. Ahuja states that he dispensed a four-ounce bottle of Guaifenesin with Codeine for approximately $10, which he says is the retail value. *See* Dr. Ahuja Aff. ¶ 10. However, Levin states that the retail value of a bottle of Guaifenesin with Codeine is $13.50. *See* Levin Aff. ¶ 26. The court finds Levin to be more credible than Dr. Ahuja. Furthermore, Dr. Ahuja states that Guaifenesin with Codeine cost him approximately $10 to buy, *see* Dr. Ahuja Aff. ¶ 10, and Levin does not dispute this cost, *see* Levin Aff. ¶ 26. The court finds that, if Dr. Ahuja sold the unaccounted-for Guaifenesin with Codeine, he would have sold it for approximately $13.50 per bottle, making a profit of approximately $3.50 per bottle. Dr. Ahuja failed to account for 58 bottles of Guaifenesin with Codeine. *See* Am. Compl. Count XV. Dr. Ahuja thus would have made a profit of approximately $203 by dispensing the unaccounted-for Guaifenesin with Codeine.

Dr. Ahuja did not testify as to how much he typically charged clients for, or how much he himself paid for, Testosterone Cypionate or Zolpidem Tartrate. *See* Dr. Ahuja Aff. The court adopts Levin's estimates of the suggested retail value of these drugs. Levin estimates that the retail value of all the unaccounted-for Testosterone Cypionate was $169.18, and that the

retail value of all the unaccounted-for Zolpidem Tartrate was $1,860. *See* Levin Aff. ¶ 26. Assuming that Dr. Ahuja would have had to pay roughly one-third the retail cost in order to buy these drugs himself, the court estimates that Dr. Ahuja could have made a profit of approximately $112.79 from the unaccounted-for Testosterone Cypionate and $1,240 from the unaccounted-for Zolpidem Tartrate.

The total profit Dr. Ahuja would have made by "legitimately" dispensing the unaccounted-for drugs is approximately $3,150. The court concludes that this $3,150 figure is the appropriate amount of profit to consider in applying the *Advance Pharmaceutical* standard. In adopting this profit figure, the court acknowledges that this figure is necessarily an estimation, as neither party has presented definitive evidence that the profit Dr. Ahuja made from his violations is in fact a function of the retail value of the unaccounted-for drugs, minus the price Dr. Ahuja paid for the drugs. For instance, the court lacks evidence that Dr. Ahuja in fact sold all the unaccounted-for drugs at their retail value and did not give any away for free, sell any for less than retail value, consume any himself or, as Dr. Ahuja suggests, have any stolen from him. In these scenarios, Dr. Ahuja would have made less than the above-estimated profit from the unaccounted-for drugs. Similarly, the court lacks conclusive evidence that Dr. Ahuja sold the unaccounted-for drugs for only their retail value and did not sell them for a higher street price, to individuals who did not have a medical need.[19] In this scenario,

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[19] Dr. Ahuja did not keep, or did not produce to the court, medical records or other notes regarding his dispensing of the missing medications.

Dr. Ahuja would have made much more than the above-estimated profit from the unaccounted-for drugs. However, in the absence of evidence supporting either that Dr. Ahuja's profit was less than the retail value minus the price he paid, or that his profit was more than this figure, it is most reasonable to estimate that Dr. Ahuja's profit from his violations was the retail value of the unaccounted-for drugs minus the price he paid for them.

D. Ability to Pay

The court finds that Dr. Ahuja's annual adjusted gross income can be expected to be about $200,000 per year in the coming years, for the reasons that follow.

Dr. Ahuja's 2015 Individual Income Tax Return reflects an adjusted gross income of $155,705. *See* U.S. Individual Tax Return, 2015 (Def. Ex. EE) at 1; Stefan Peleschuk ("Peleschuk") Aff. (Def. Ex. E) ¶ 6. However, his 2014 Individual Income Tax Return reflects an adjusted gross income of $239,692. *See* U.S. Individual Tax Return, 2014 (Def. Ex. DD) at 1; Peleschuk Aff. ¶ 7. The court does not credit Dr. Ahuja's insistence that this 2014 income will not be representative of his income going forward, due to Dr. Ahuja's general lack of credibility, as well as the fact that Dr. Ahuja gave two different explanations to the court for why his 2014 income should be considered an aberration. *Compare* Dr. Ahuja Aff. at 10 ¶ 13 (stating that his 2014 income was an aberration because his ex-wife became too disabled to work, and so he temporarily took over her responsibilities at Darien Immediate Medical Center and received additional compensation for doing so, before passing those responsibilities on to Nicholas); *with* Tr. at 119-20

(stating that his 2014 income was an aberration because he sold some property that year, and also because his ex-wife allowed him to take more money from Darien Immediate Medical Center that year to help him pay certain legal expenses, with the understanding that she would take extra money in the future). However, the court does acknowledge that Dr. Ahuja's income in 2014 was higher than in the 2015 and in 2013. Dr. Ahuja's 2013 Individual Income Tax Return reflects an adjusted gross income of $215,037. *See* U.S. Individual Tax Return, 2013 (Def. Ex. CC) at 1; Peleschuk Aff. ¶ 8. Taking an average of these three amounts, the court concludes that Dr. Ahuja's annual adjusted gross income can be expected to be approximately $200,000 per year.

Dr. Ahuja, who is sixty-three years old, testified that a variety of health problems, such as high blood pressure, depression, acid reflux, and poor hearing, "threaten to impact" his "ability to practice medicine in the imminent future." Dr. Ahuja Aff. at 11 ¶ 12. However, in the absence of any evidence as to his health demonstrating that Dr. Ahuja will likely have to stop practicing medicine in the imminent future, the court does not rely on Dr. Ahuja's self-serving speculation. He is still practicing, and even testified that he increased his work load when his ex-wife stopped working. *See id.* at 10 ¶ 13. The court finds that Dr. Ahuja has not provided credible evidence that he will be unable to continue working in the immediate future.

The court is unable to make a definitive finding as to the full extent of Dr. Ahuja's assets, due to Dr. Ahuja's failure to provide certain information. *See Provost v. City of Newburgh*, 262 F.3d 146, 163 (2d Cir. 2001) ("The duty [ ] is on the defendant to present

evidence . . . of his limited resources if he wishes that factor to be weighed in the calculation of punitive damages."); *see also Fowler v. Cal. Highway Patrol*, No. 13-CV-01026 (TEH), 2014 U.S. Dist. LEXIS 112540, 2014 WL 3965027, at *6 (N.D. Cal. Aug. 13, 2014) (in imposing costs on plaintiff, disregarding plaintiff's argument "that her financial resources are scarce," because "she presents no admissible evidence supporting that she has limited financial resources"); *Lazy Oil Co. v. Witco Corp.*, 95 F. Supp. 2d 290, 318 (W.D. Pa. 1997) (in class action settlement context, where sole evidence offered as to defendant's ability to pay larger judgment had "little bearing" on the issue, presuming that defendants "have the financial resources to pay a larger judgment"). The court does not put much weight in Dr. Ahuja's assertion that he has "virtually no financial assets." *Id.* at 9 ¶ 12. First, the court notes that, while Dr. Ahuja testified that he owns "no real estate, except for" his "1% share in the assets of Ahuja Holdings, LLC," Dr. Ahuja does not state in his Affidavit the value of any other property he owns, such as stocks. *See* Dr. Ahuja Aff. at 9-10 ¶ 12. Dr. Ahuja did not state in his Affidavit or at the hearing that he owns no stocks or other such property. *See id.* ¶ 12; Tr. at 108-10, 118-21. Dr. Ahuja's accountant, Peleschuk, and Dr. Ahuja, both indicated that Dr. Ahuja at times has owned stocks. *See* Peleschuk Aff. ¶ 6, 8 ("He took losses from the stocks he owns in [2015] . . . He gained a profit of $65K in earnings from stocks that he owned in [2013]."); Tr. at 119, 166-67 (containing, first, testimony by Dr. Ahuja that, "I believe I sold some property," and, later, in response to this court's comment that "I heard testimony that he had sold real estate," a response by defense counsel that the earlier testimony

containing the term "property" "was referring to stock").

While Dr. Ahuja did not mention cars in his Affidavit, *see* Dr. Ahuja Aff., Dr. Ahuja admitted on cross-examination that he owns both a BMW and a Mercedes, *see* Tr. at 107-08. Dr. Ahuja states that he has "two IRA retirement accounts, each with an approximate value of $10,000.00," and "two bank accounts, one . . . with a present balance of approximately $1,500.00 and the other . . . with a present balance of approximately $4,000.00." Dr. Ahuja Aff. at 10 ¶ 12. The court notes that Dr. Ahuja has not stated whether he transferred funds away from himself in order to be able to make this statement to the court regarding the "present balance" of his bank accounts. *Id.* at 10 ¶ 12. Dr. Ahuja has been known to transfer a large quantity of real property away from himself in the past, *see id.* at 10 ¶ 12 (stating that Dr. Ahuja conveyed a 99% interest in a trust containing all the real estate he "acquired over the course of" his life to his son, Nicholas, in 2009), although there is no evidence before this court that Dr. Ahuja made those transfers for improper motives.

Due to the lack of convincing evidence that Dr. Ahuja will become unable to work in the immediate future, or that Dr. Ahuja has no assets, the court concludes on the record before it that Dr. Ahuja has significant earning capacity and some other financial resources.

V. Conclusions of Law

A. Number of Violations and Maximum Penalties

As described in more detail below, Dr. Ahuja has engaged in a substantial number of violations of subsections 842(a)(1) and 842(a)(5) of title 21 of the United States Code. The maximum combined penalty

that Dr. Ahuja faces for these violations is $10,010,000.[20] At the hearing, and in a Motion for Default Judgment (Doc. No. 14), the Government asked the court to impose a $496,500 penalty. *See* Tr. at 143; Mot. for Default ¶ 10.

1. Counts One through Eighteen

As detailed below, Counts One through Eighteen involve 961 violations, each of which carry a maximum penalty of $10,000.

The Amended Complaint sets forth in Counts One through Eight violations of section 842(a)(5), for failure to maintain controlled substance receipt records for various shipments. *See* Am. Compl. Counts I-VIII. The maximum penalty for a violation of section 842 (a)(5) is $10,000. *See* 21 U.S.C. § 842(c)(1)(B). Thus, the maximum penalty for each of the violations in these Counts is $10,000. *See* 21 U.S.C. § 842(c)(1)(B); *see also* Am. Compl. at 7. Absent evidence suggesting that multiple shipments represented a single purchase,

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[20] In its original Complaint (Doc. No. 2), the Government asked the court to impose a total penalty of $10,010,000—the maximum penalty allowable. *See* Compl. at 7-8 (asking court to impose penalty of $9,610,000 for violations in Counts I through XVIII, and $400,000 for violations in Counts XIX through XXV). However, the Amended Complaint inexplicably asked the court to impose a total penalty of $10,015,000. *See* Am. Compl. at 7-8 (asking court to impose penalty of $9,640,000 for violations in Counts I through XVIII, and $375,000 for violations in Counts XIX through XXV). The Government did not explain in its Motion to Amend (Doc. No. 97) or Memorandum in Support of Motion to Amend (Doc. No. 97-1) that it was changing the requested penalty amount, nor why. To the contrary, the Government stated that it sought to make "technical and non-substantive amendments . . . to clarify the charges," and that Dr. Ahuja was "not materially impacted by the amendments to the complaint." Mem. in Supp. of Mot. to Am. at 1.

see United States v. Bizga, No. 1:13-CV-206, 2014 U.S. Dist. LEXIS 185900, 2014 WL 11370407, at *2 (N.D. Ohio Apr. 8, 2014) ("When assessing penalties for failure to record or report purchases of controlled substances, each purchase counts as a separate violation."), the court considers each shipment in these Counts to be a separate violation, *see United States v. Stidham*, 938 F. Supp. 808, 816 (S.D. Ala. 1996) ("[F]ailure to record the number and dates of the items received as to each of the seventeen shipments amounts to seventeen [] violations."). Counts One through Eight involve fifty-three shipments. *See* Am. Compl. Counts I-VIII. Counts One through Eight thus involve fifty-three violations combined, and the maximum penalty for these counts, combined, is $530,000.

The Amended Complaint does not explicitly describe Counts Nine through Eighteen as section 842(a)(5) violations.[21] *See* Am. Compl. Counts IX-XVIII. However, each of Counts Nine through Eighteen describes conduct that violates section 842(a)(5), which makes it unlawful to "refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under" the CSA. 21 U.S.C. § 842(a)(5).[22] Thus, the maximum penalty for

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[21] However, the Amended Complaint asked the court to enter "a civil penalty of $10,000 for each of the violations and occurrences set forth in" these Counts, citing section 842(c)(1) of title 21 of the United States Code. Am. Compl. at 7. Section 842(c)(1) lists this $10,000 figure as the penalty for a violation of section 842(a)(5). *See* 21 U.S.C. § 842(c)(1)(B).

[22] Count Nine, which is failure to keep separate records for certain controlled substances, *see* Am. Compl. Count IX; Count Ten, which is failure "to perform and maintain a biennial inventory of controlled substances," Am. Compl. Count X; and

each of the violations in Counts Nine through Eighteen is $10,000 per violation.

The court treats Count Nine and Count Ten as each involving a single violation, because each of these two Counts allege an overall failure to create or keep one type of record. Counts Nine and Ten thus involve a total of two CSA violations, and the maximum penalty for these two Counts combined is $20,000.

As for Counts Eleven through Eighteen, the court treats each individual dispensation as a separate violation. *See United States v. Paskon*, No. 4:07-CV-1161 (CEJ), 2008 U.S. Dist. LEXIS 91045, 2008 WL 4948458, at *2 (E.D. Mo. Nov. 10, 2008) (treating one unlawful prescription as one violation); *United States v. Salcedo*, No. 02-CV-1095 (FB) (VVP), 2003 U.S. Dist. LEXIS 8561, 2003 WL 21196843, at *2 (E.D.N.Y. Feb. 19, 2003) ("The issuance of each of the [] prescriptions constituted a separate violation."); *United States v. Akhtar*, 95 F. Supp. 2d 668, 669, 673 (S.D. Tex. 1999) (treating four unlawful sales as "four violations"). However, because Dr. Ahuja did not maintain accurate dispensing records or properly complete dispensation logs, *see* Am. Compl. Count XI-XVIII, the court does not know how many drugs were dispensed at one time in Counts Eleven through Eighteen, and thus does not know how many separate dispensations are represented by these counts. Where "the defendant's own failure to keep any records makes it impossible to determine [the] number of violations,"

Counts Eleven through Eighteen, which are either failures to maintain accurate dispensing records or failures to properly complete dispensation logs, *see* Am. Compl. Count XI-XVIII, all constitute failures "to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required," 21 U.S.C. § 842(a)(5).

a court in the Northern District of Ohio decided it was "fair that all inferences be drawn against defendant and that the Court assume the worst-case scenario" with regard to the number of violations. *United States v. Heim*, No. 5:13-CV-210, 2014 U.S. Dist. LEXIS 7673, 2014 WL 245357, at *5 (N.D. Ohio Jan. 22, 2014).[23] Here, Counts Eleven through Eighteen involved 141 bottles and 2 vials of drugs unaccounted for, and 763 bottles of drugs dispensed without proper logging. *See* Am. Compl. Counts XI-XVIII. The court thus treats Counts Eleven through Eighteen as 906 violations. The maximum penalty for Counts Eleven through Eighteen combined is $9,060,000. The court thus finds that the maximum penalty for all violations in Counts One through Eighteen is $9,610,000.

2. Counts Nineteen through Twenty-Three

Counts Nineteen through Twenty-Three allege violations of section 842(a)(1). The maximum penalty for the violations in each of these Counts is $25,000. *See* 21 U.S.C. § 842(c)(1)(A); *see also* Am. Compl. at 7-8. Counts Nineteen through Twenty-Three involved four dispensations to Gurpreet, *see* Am. Compl. Count XIX; two dispensations to Sunny, *see id.* Count XX; five prescriptions to Nicholas, *see id.* Count XXI; three prescriptions to Uttam, *see id.* Count XXII; and

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[23] *Heim* treated each individual tablet as a separate violation, for a total of 11,500 violations, in light of the facts of the particular case. 2014 U.S. Dist. LEXIS 7673, 2014 WL 245357 at *5. The court finds that, to charge Dr. Ahuja with a separate violation for every individual pill involved in his violations would be excessive here, but accepts the general principal that uncertainty resulting from Dr. Ahuja's failure to keep records should lead to assumptions in the Government's favor. The court thus treats each bottle or vial in these Counts as a separate violation.

two dispensations to either Nicholas or Uttam, *see id.* Count XXIII. The court thus treats Counts Nineteen through Twenty-Three as sixteen CSA violations. The court thus finds that the maximum penalty for all the violations in Counts Nineteen through Twenty-Three combined is $400,000.

B. Culpability

Culpability can be conceptualized as the "good or bad faith of the defendant[ ]," *see Advance Pharmaceutical*, 391 F.3d at 400 (internal quotation marks omitted), "the willfulness of the violations," *United States v. Queen Village Pharmacy*, 1990 U.S. Dist. LEXIS 14425, 1990 WL 165907 at *2, or whether the unlawful acts were "deliberate," 1990 U.S. Dist. LEXIS 14425, [WL] at *3.

The number of violations and the length of time involved affects the determination of culpability. "[T]he level of culpability of the defendant" was found "to be relatively high in view of the numerous repeated violations of the [Controlled Substances] Act over an extended period of time." *United States v. Salcedo*, No. 02-CV-1095 (FB) (VVP), 2003 U.S. Dist. LEXIS 8561, 2003 WL 21196843, at *2 (E.D.N.Y. Feb. 19, 2003). The defendant in *Salcedo* had engaged in thirty-two violations over a span of one year and nine months. *See* 2003 U.S. Dist. LEXIS 8561, [WL] at *2. Here, Dr. Ahuja has engaged in over 1,000 violations, spanning a three-year period from February 21, 2011, to February 21, 2014. *See* Am. Compl. Counts I-XXIII.

Even where the "raw number of unaccounted for [ ] tablets seems shockingly high," however, a court may "compare[ ]" that number "to the total number of tablets received" by the defendant, to determine the percentage of drugs unaccounted for. *Queen Village*, 1990 U.S.

Dist. LEXIS 14425, 1990 WL 165907 at *3. A lower percentage of drugs unaccounted for suggests less culpability. *See* 1990 U.S. Dist. LEXIS 14425, [WL] at *3. Here, the unaccounted-for Alprazolam represented 9.83% of Dr. Ahuja's supply, *see* Am. Compl. Count XI; the unaccounted-for Hydrocodone Bitartrate with Acetaminophen represented 17.5% of his supply, *see id.* Count XIII; the unaccounted-for Guaifenesin with Codeine Phosphate represented 27.36% of his supply, *see id.* Count XV; the unaccounted-for Testosterone Cypionate represented 100% of his supply, *see id.* Count XVII; and the unaccounted-for Zolpidem Tartrate also represented 100% of his supply, *see id.* Count XVIII. These are significant percentages, a fact which weighs in favor of a stiff penalty.

On the other hand, in assessing a doctor's culpability for failure to keep biennial inventories, the fact that the doctor attempted to keep these inventories can weigh in his favor. *See* 1990 U.S. Dist. LEXIS 14425, [WL] at *3. Dr. Ahuja claims that he attempted to keep records. *See* Dr. Ahuja Aff. ¶ 7. However, the court views his attempts as almost non-existent.

The court concludes that Dr. Ahuja's level of culpability is extremely high in this case. While Dr. Ahuja's culpability is not as high as that of a physician who intentionally sells controlled substances to drug addicts for non-medical uses, Dr. Ahuja's negligence is about as gross as the court can imagine. The admitted violations, and the evidence adduced, show that Dr. Ahuja engaged in behaviors which combine to demonstrate gross negligence, indeed recklessness, in dealing with controlled substances.

C. Public Harm

"[T]he public harm caused by the violations,"

also phrased as "the injury to the public," includes considerations such as the extent to which a doctor's actions "facilitate[ed] the diversion of" pharmaceuticals to improper uses. *Advance Pharmaceutical*, 391 F.3d at 399. Such a diversion to improper uses is especially problematic if the particular drug "would cause" a great deal of harm "in the illegal [drug] market," and if this diversion to improper users could have been largely prevented by the doctor following the law. *United States v. Global Distributors*, 498 F.3d 613, 620-21 (7th Cir. 2007). However, the mere fact that "prescription drug abuse" is "harmful to the public" will not weigh in favor of a stricter penalty where there is no evidence that the doctor's improper behavior has played a role in such drug abuse. *See United States v. Butterbaugh*, No. C14-515 (TSZ), 2015 U.S. Dist. LEXIS 102808, 2015 WL 4660096, at *7 (W.D. Wash. Aug. 5, 2015). While the risk of prescription drug abuse is present here, as discussed above, the court does not find that Dr. Ahuja was running purely a "pill factory." *See, e.g.*, *Duprey*, 652 F. App'x at 108-09. It appears that he ran a clinic with patients other than those requiring the medications in question.

The Government initially asserted that, "[i]n order to quantify the harm to the public, courts have permitted the United States to include [ ] an estimate of the United States' investigative costs." Pl.'s Mem. at 3. However, the Government's Memorandum does not cite any cases supportive of this assertion. *See id.* at 3. The court is aware of a Northern District of New York case that, in calculating a civil penalty for failure to comply with an Environmental Protection Agency information request, held that "[d]elaying [an] investigation . . . constitute[s] injury to the public." *United States v. Timmons Corp.*, No. CIV-103-CV-

951 (RFT), 2006 U.S. Dist. LEXIS 7642, 2006 WL 314457 at *16 (N.D.N.Y. Feb. 8, 2006). The court does not consider *Timmons* to be on point, however.[24] At a pre-hearing conference, the court asked the Government to support its assertion, and the Government asked for more time to do so. However, the Government did not submit additional briefing on this topic. At the hearing, Government counsel admitted that, "there is not a specific reference that I'm aware of that allows specifically investigative costs." Tr. at 4. The court thus does not consider the cost of the investigation in assessing the public harm in this case.[25]

The Government also asserts that, "[i]n order to quantify the harm to the public, courts have permitted the United States to include . . . an estimate of the street value of the controlled substances in the illegal drug trade." Pl.'s Mem. at 3. This is true (1) where the evidence supports a finding that drugs were diverted to illegal uses, and (2) where, although the evidence is insufficient to support a finding that diversion occurred, there is nonetheless a significant risk that such a diversion may have occurred.

Where drugs are diverted to illegal uses, courts

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[24] In calculating a civil penalty for refusal to allow state officials on property, the Sixth Circuit listed "injury to the public" and "cost to the state of prosecuting," separately, *United States v. Taylor*, 8 F.3d 1074, 1078 (6th Cir. 1993), thus suggesting that at least the cost of prosecuting is excluded from the meaning of injury to the public, at least in that context.

[25] While Dr. Ahuja's contradictory answers may not have been calculated to facilitate the investigation, the Government has failed to present evidence that Dr. Ahuja actually delayed the investigation, such as evidence that Dr. Ahuja caused investigators to spend time on false leads.

consider the street value of the drugs in determining an appropriate penalty. For instance, the Seventh Circuit found that the fact that drugs were "converted into almost half a million dollars' worth of methamphetamine . . . cut[ ] in favor of a stiff penalty." *Global Distributors*, 498 F.3d at 620-21 (internal quotation marks omitted). Similarly, a court in the Eastern District of New York assessed a penalty for civil CSA violations which was calculated to match a high estimate of the approximate street value of all drugs prescribed in violation of the CSA. *See Salcedo*, 2003 U.S. Dist. LEXIS 8561, 2003 WL 21196843, at *2. Specifically, where a doctor prescribed 3,200 tablets and a witness testified that "each tablet can be sold on the street for between $5 and $8," the court assessed a penalty of $25,600, calculated by multiplying the number of tablets by the higher estimate of eight dollars. 2003 U.S. Dist. LEXIS 8561, [WL] at *2. In *Salcedo*, while the court did not say so explicitly, the defendant presumably diverted the drugs to improper purposes: "[T]he prescriptions were issued in the name of a patient who was not under the direct care of the defendant," and "the address listed by the defendant on each prescription was not the proper address for the patient; the address listed was in Queens, New York, but the purported patient was living in the Philippines throughout the time when the prescriptions were written." 2003 U.S. Dist. LEXIS 8561, [WL] at *2. The court did not explicitly state that the doctor's prescribing of drugs in the name of a non-patient who lived outside of the country, coupled with the use of a false address, evidenced that the drugs were diverted. 2003 U.S. Dist. LEXIS 8561, [WL] at *2. However, the court implied that the defendant had likely sold the drugs on the street, by stating,

after mentioning the street value, that the defendant "could have grossed as much as $25,600 from the sale" of the tablets. 2003 U.S. Dist. LEXIS 8561, [WL] at *2. Lastly, where drugs disappeared from pharmacies, a court in the District of Massachusetts assessed the "harm to the public" in part by discussing the street value of the missing drugs. *United States v. Poulin*, 926 F. Supp. 246, 254-55 (D. Mass. 1996). In *Poulin*, the drugs were "reported stolen." *Id.* at 249. Again, while the court did not explicitly state that the fact of the drugs being stolen supported a finding that they were diverted, the court implied that the stolen drugs were diverted, by stating that "[t]he disappearance of these drugs constitutes a serious public health risk," due to the danger of drug abuse. *Id.* at 254.

A court may also consider the street value of the drugs in determining an appropriate penalty where, although the evidence is insufficient to support a finding that diversion occurred, there is nonetheless a significant risk that such a diversion may have occurred. A court in the Northern District of Ohio found a "significant risk that [ ] tablets of hydrocodone"—which the court noted is "a highly abused and highly controlled substance"—were diverted to illegal channels and rendered untraceable. *Bizga*, 2014 U.S. Dist. LEXIS 185900, 2014 WL 11370407, at *6. The court determined "that a fine which treble[d] the street value of the [ ] drugs would certainly be reasonable for the recording violations relating to the dispensing of the[ ] tablets." 2014 U.S. Dist. LEXIS 185900, [WL] at *6 (nonetheless assessing lower penalty, due to insufficient ability to pay). However, a court in the Western District of Washington has refused to consider the street value of improperly-prescribed drugs in its assessment of harm to the

public, where there was no evidence that the drugs were distributed or dispensed for non-medical purposes. *Butterbaugh*, 2015 U.S. Dist. LEXIS 102808, 2015 WL 4660096, at *7.

Here, while there is insufficient evidence to find by a preponderance of the evidence that any drugs were in fact diverted or abused, the court concludes that there is a significant risk that such diversion may have occurred. For instance, if Dr. Ahuja is correct that his drugs were stolen, it is clear that they were distributed illegally.

In assessing harm to the public, courts also consider the dangerousness of the drugs involved in the CSA violations. As mentioned above, a court in the Northern District of Ohio considered the fact that Hydrocodone is "highly abused" in weighing the harm to the public. *Bizga*, 2014 U.S. Dist. LEXIS 185900, 2014 WL 11370407, at *6. Similarly, a court in the District of Massachusetts assessed the "harm to the public" in part by discussing the fact that "the drugs that disappeared from the [] pharmacies are drugs with a very high abuse potential," and that the abuse of some of the missing drugs "can cause serious trauma and even death to abusers." *Poulin*, 926 F. Supp. at 254-55. "[H]ighly abused" Hydrocodone, *Bizga*, 2014 U.S. Dist. LEXIS 185900, 2014 WL 11370407, at *6, is one of the drugs involved in the violations here. *See* Am. Compl. Counts II, XIII, XIX, XII. It does not require a citation to conclude that the illicit sale of controlled substances has enormous costs to individuals and society.

The court finds that the level of public harm weighs in favor of imposition of a severe penalty, because (1) Dr. Ahuja dispensed drugs that had a high

potential for abuse, without any, let alone the requisite degree of, care to ensure that the drugs would not be misused, and (2) a risk of diversion of these drugs is present.

D. Profit

Courts consider the extent of "defendant's profits from the violations" in setting the penalty for civil CSA violations. *Advance Pharmaceutical*, 391 F.3d 377, 399 (2d Cir. 2004). For instance, a court acts "well within its discretion" when it selects a civil penalty designed to "divest defendants of all profits made in connection with the [unlawful] transactions." *Id.* at 399-400.

Here, the court does not consider profit to be a major factor in determining Dr. Ahuja's penalty, because the evidence does not support a finding that Dr. Ahuja made a large profit as a result of his violations.

E. Ability to Pay

In setting the penalties amount, a court considers whether the "defendant['s] financial condition evidence[s] an ability to pay" the penalty under consideration. *Advance Pharmaceutical*, 391 F.3d at 400. For example, in *Advance Pharmaceutical*, the district court reasonably determined that the defendant's operations had not "been so adversely affected by the enforcement action that they could not pay" the amount that the district court was considering and properly credited "expert opinion indicating the company's ability to continue operating profitably as well as evidence that defendants had engaged in a series of suspicious loans to shield" some assets. *Id.* at 400. The Circuit thus concluded that the district court's penalty was not excessive. *See id.* at 400. Con-

versely, where a doctor had only a "moderate ability to pay a civil fine," a court in the Northern District of Ohio decided to assess a fine that only doubled the street value of the drugs involved in the doctor's violations—even where a fine that trebled the street value of these drugs would "certainly" have been "reasonable." *Bizga*, 2014 U.S. Dist. LEXIS 185900, 2014 WL 11370407, at *6.

The burden is on the defendant to produce evidence of an inability to pay. *See Motorola Credit Corp. v. Uzan*, 509 F.3d 74, 84 (2d Cir. 2007) ("The incompleteness of the record as to [a defendant's] net worth is not a basis for reducing the punitive damages award against him, for it is the defendant's burden to show that his financial circumstances warrant a limitation of the award . . . [T]he decided cases and sound principle require that a defendant carry the burden of showing his modest means—facts peculiarly within his power—if he wants this considered in mitigation of damages."); *Provost*, 262 F.3d at 163 ("The duty [ ] is on the defendant to present evidence . . . of his limited resources if he wishes that factor to be weighed in the calculation of punitive damages.").

Dr. Ahuja introduced some evidence about his financial ability, or lack thereof. However, the court is not persuaded that he is incapable of paying a substantial penalty. He has substantial future earnings and appears to have some assets. The court finds that Dr. Ahuja has not met his burden of showing an inability to pay the penalty that the court will impose upon him.

VI. Conclusion

The court finds that Dr. Ahuja's level of culpability weighs in favor of imposition of a substantially stringent

penalty, because Dr. Ahuja engaged in numerous violations over several years demonstrated gross negligence, even reckless conduct, and provided misleading information to investigators. The court finds that the level of public harm weighs in favor of imposition of a severe penalty, as well. The court finds that the profit factor weighs in favor of imposition of a lighter penalty, because there is inadequate evidence to support a finding that Dr. Ahuja made a substantial profit from his violations. Lastly, the court finds that Dr. Ahuja has the ability to pay a substantial penalty, that the court plans to impose. The court considers and weighs these factors together in assessing its penalty.

Dr. Ahuja is hereby ORDERED to pay a civil penalty of $200,000, and to comply with all federal laws and regulations pertaining to receipts, dispensations, and inventories of controlled substances in the future.

SO ORDERED.

Dated at New Haven, Connecticut this 5th day of May, 2017.

/s/ Janet C. Hall
U.S. District Judge

RELEVANT STATUTORY PROVISIONS AND FEDERAL REGULATIONS

STATUTORY PROVISIONS

21 U.S.C. § 827—Records and Reports of Registrants

(a) Inventory. Except as provided in subsection (c)—

(1) every registrant under this title shall, on the effective date of this section, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply;

(2) on the effective date of each regulation of the Attorney General controlling a substance that immediately prior to such date was not a controlled substance, each registrant under this title manufacturing, distributing, or dispensing such substance shall make a complete and accurate record of all stocks thereof on hand; and

(3) on and after the effective date of this section, every registrant under this title manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold,

delivered, or otherwise disposed of by him, except that this paragraph shall not require the maintenance of a perpetual inventory.

(b) Availability of records. Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

(c) Nonapplicability. The foregoing provisions of this section shall not apply—

(1)

(A) to the prescribing of controlled substances in schedule II, III, IV, or V by practitioners acting in the lawful course of their professional practice unless such substance is prescribed in the course of maintenance or detoxification treatment of an individual; or

(B) to the administering of a controlled substance in schedule II, III, IV, or V unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges his patients, either separately or together with charges for other professional services, for substances so dispensed or administered or unless such substance is administered in the course of main-

tenance treatment or detoxification treatment of an individual;

(2)

(A) to the use of controlled substances, at establishments registered under this title which keep records with respect to such substances, in research conducted in conformity with an exemption granted under section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355(i) or 360b(j)];

(B) to the use of controlled substances, at establishments registered under this title which keep records with respect to such substances, in preclinical research or in teaching; or

(3) to the extent of any exemption granted to any person, with respect to all or part of such provisions, by the Attorney General by or pursuant to regulation on the basis of a finding that the application of such provisions (or part thereof) to such person is not necessary for carrying out the purposes of this title.

Nothing in the Convention on Psychotropic Substances shall be construed as superseding or otherwise affecting the provisions of paragraph (1)(B), (2), or (3) of this subsection.

(d) Periodic reports to Attorney General.

(1) Every manufacturer registered under section 303 [21 U.S.C. § 823] shall, at such time or times and in such form as the Attorney General may require, make periodic reports to the Attorney General of every sale, delivery, or other disposal by him of any controlled substance, and each distributor shall make such reports with respect to narcotic controlled substances, identifying by the

registration number assigned under this title the person or establishment (unless exempt from registration under section 302(d) [21 U.S.C. § 822(d)]) to whom such sale, delivery, or other disposal was made.

(2) Each pharmacy with a modified registration under section 303(f) [21 U.S.C. § 823(f)] that authorizes the dispensing of controlled substances by means of the Internet shall report to the Attorney General the controlled substances it dispenses, in the amount specified, and in such time and manner as the Attorney General by regulation shall require, except that the Attorney General, under this paragraph, may not require any pharmacy to report any information other than the total quantity of each controlled substance that the pharmacy has dispensed each month. For purposes of this paragraph, no reporting shall be required unless the pharmacy has met 1 of the following thresholds in the month for which the reporting is required:

(A) 100 or more prescriptions dispensed.

(B) 5,000 or more dosage units of all controlled substances combined.

(e) Reporting and recordkeeping requirements of drug conventions. In addition to the reporting and recordkeeping requirements under any other provision of this title, each manufacturer registered under section 303 [21 U.S.C. § 823] shall, with respect to narcotic and nonnarcotic controlled substances manufactured by it, make such reports to the Attorney General, and maintain such records, as the Attorney General may require to enable the United States to meet its obligations under articles 19 and 20 of the Single

Convention on Narcotic Drugs and article 16 of the Convention on Psychotropic Substances. The Attorney General shall administer the requirements of this subsection in such a manner as to avoid the unnecessary imposition of duplicative requirements under this title on manufacturers subject to the requirements of this subsection.

(f)

(1) The Attorney General shall, not less frequently than quarterly, make the following information available to manufacturer and distributor registrants through the Automated Reports and Consolidated Orders System, or any subsequent automated system developed by the Drug Enforcement Administration to monitor selected controlled substances:

(A) The total number of distributor registrants that distribute controlled substances to a pharmacy or practitioner registrant, aggregated by the name and address of each pharmacy and practitioner registrant.

(B) The total quantity and type of opioids distributed, listed by Administration Controlled Substances Code Number, to each pharmacy and practitioner registrant described in subparagraph (A).

(2) The information required to be made available under paragraph (1) shall be made available not later than the 30th day of the first month following the quarter to which the information relates.

(3)

(A) All registered manufacturers and distributors shall be responsible for reviewing the information made available by the Attorney

General under this subsection.

(B) In determining whether to initiate proceedings under this title against a registered manufacturer or distributor based on the failure of the registrant to maintain effective controls against diversion or otherwise comply with the requirements of this title or the regulations issued thereunder, the Attorney General may take into account that the information made available under this subsection was available to the registrant.

(g) Investigational uses of drugs; procedures. Regulations under sections 505(i) and 512(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§ 355(i) and 360b(j)], relating to investigational use of drugs, shall include such procedures as the Secretary, after consultation with the Attorney General, determines are necessary to insure the security and accountability of controlled substances used in research to which such regulations apply.

(h) Change of address. Every registrant under this title shall be required to report any change of professional or business address in such manner as the Attorney General shall by regulation require.

(i) Reporting requirements for GHB. In the case of a drug product containing gamma hydroxybutyric acid for which an application has been approved under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355], the Attorney General may, in addition to any other requirements that apply under this section with respect to such a drug product, establish any of the following as reporting requirements:

(1) That every person who is registered as a

manufacturer of bulk or dosage form, as a packager, repackager, labeler, relabeler, or distributor shall report acquisition and distribution transactions quarterly, not later than the 15th day of the month succeeding the quarter for which the report is submitted, and annually report end-of-year inventories.

(2) That all annual inventory reports shall be filed no later than January 15 of the year following that for which the report is submitted and include data on the stocks of the drug product, drug substance, bulk drug, and dosage forms on hand as of the close of business December 31, indicating whether materials reported are in storage or in process of manufacturing.

(3) That every person who is registered as a manufacturer of bulk or dosage form shall report all manufacturing transactions both inventory increases, including purchases, transfers, and returns, and reductions from inventory, including sales, transfers, theft, destruction, and seizure, and shall provide data on material manufactured, manufactured from other material, use in manufacturing other material, and use in manufacturing dosage forms.

(4) That all reports under this section must include the registered person's registration number as well as the registration numbers, names, and other identifying information of vendors, suppliers, and customers, sufficient to allow the Attorney General to track the receipt and distribution of the drug.

(5) That each dispensing practitioner shall maintain for each prescription the name of the pre-

scribing practitioner, the prescribing practitioner's Federal and State registration numbers, with the expiration dates of these registrations, verification that the prescribing practitioner possesses the appropriate registration to prescribe this controlled substance, the patient's name and address, the name of the patient's insurance provider and documentation by a medical practitioner licensed and registered to prescribe the drug of the patient's medical need for the drug. Such information shall be available for inspection and copying by the Attorney General.

(6) That section 310(b)(3) [21 U.S.C. § 830(b)(3)] (relating to mail order reporting) applies with respect to gamma hydroxybutyric acid to the same extent and in the same manner as such section applies with respect to the chemicals and drug products specified in subparagraph (A)(i) of such section.

(j) All of the reports required under this section shall be provided in an electronic format.

21 U.S.C. § 801—Congressional Findings and Declarations: Controlled Substances

The Congress makes the following findings and declarations:

(1) Many of the drugs included within this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

(2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.

(3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because—

(A) after manufacture, many controlled substances are transported in interstate commerce,

(B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and

(C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.

(4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.

(5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

(6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.

(7) The United States is a party to the Single Convention on Narcotic Drugs, 1961, and other

international conventions designed to establish effective control over international and domestic traffic in controlled substances.

21 U.S.C. § 842—Prohibited acts B

(a) Unlawful acts. It shall be unlawful for any person—

(1) who is subject to the requirements of part C [21 U.S.C. §§ 821 et seq.] to distribute or dispense a controlled substance in violation of section 309 [21 U.S.C. § 829];

(2) who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration;

(3) who is a registrant to distribute a controlled substance in violation of section 305 of this title [21 U.S.C. § 825];

(4) to remove, alter, or obliterate a symbol or label required by section 305 of this title [21 U.S.C. § 825];

(5) to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this title or title III;

(6) to refuse any entry into any premises or inspection authorized by this title or title III;

(7) to remove, break, injure, or deface a seal placed upon controlled substances pursuant to section 304(f) or 511 [21 U.S.C. § 824(f) or 881] or to remove or dispose of substances so placed under seal;

(8) to use, to his own advantage, or to reveal,

other than to duly authorized officers or employees of the United States, or to the courts when relevant in any judicial proceeding under this title or title III, any information acquired in the course of an inspection authorized by this title concerning any method or process which as a trade secret is entitled to protection, or to use to his own advantage or reveal (other than as authorized by section 310) any information that is confidential under such section;

(9) who is a regulated person to engage in a regulated transaction without obtaining the identification required by [section] 310(a)(3) [21 U.S.C. § 830(a)(3)];

(10) negligently to fail to keep a record or make a report under section 310 [21 U.S.C. § 830] or negligently to fail to self-certify as required under section 310 [21 U.S.C. § 830];

(11) to distribute a laboratory supply to a person who uses, or attempts to use, that laboratory supply to manufacture a controlled substance or a listed chemical, in violation of this title or title III, with reckless disregard for the illegal uses to which such a laboratory supply will be put;

(12) who is a regulated seller, or a distributor required to submit reports under subsection (b)(3) of section 310 [21 U.S.C. § 830]—

(A) to sell at retail a scheduled listed chemical product in violation of paragraph (1) of subsection (d) of such section, knowing at the time of the transaction involved (independent of consulting the logbook under subsection (e)(1)(A)(iii) of such section) that the transaction is a violation; or

(B) to knowingly or recklessly sell at retail such a product in violation of paragraph (2) of such subsection (d);

(13) who is a regulated seller to knowingly or recklessly sell at retail a scheduled listed chemical product in violation of subsection (e) of such section;

(14) who is a regulated seller or an employee or agent of such seller to disclose, in violation of regulations under subparagraph (C) of section 310(e)(1) [21 U.S.C. § 830(e)(1)], information in logbooks under subparagraph (A)(iii) of such section, or to refuse to provide such a logbook to Federal, State, or local law enforcement authorities;

(15) to distribute a scheduled listed chemical product to a regulated seller, or to a regulated person referred to in section 310(b)(3)(B) [21 U.S.C. § 830(b)(3)(B)], unless such regulated seller or regulated person is, at the time of such distribution, currently registered with the Drug Enforcement Administration, or on the list of persons referred to under section 310(e)(1)(B)(v) [21 U.S.C. § 830(e)(1)(B)(v)];

(16) to violate subsection (e) of section 825 of this title [21 U.S.C. § 825]; or

(17) in the case of a registered manufacturer or distributor of opioids, to fail to review the most recent information, directly related to the customers of the manufacturer or distributor, made available by the Attorney General in accordance with section 307(f) [21 U.S.C. § 827(f)].

As used in paragraph (11), the term "laboratory supply" means a listed chemical or any chemical,

substance, or item on a special surveillance list published by the Attorney General, which contains chemicals, products, materials, or equipment used in the manufacture of controlled substances and listed chemicals. For purposes of paragraph (11), there is a rebuttable presumption of reckless disregard at trial if the Attorney General notifies a firm in writing that a laboratory supply sold by the firm, or any other person or firm, has been used by a customer of the notified firm, or distributed further by that customer, for the unlawful production of controlled substances or listed chemicals a firm distributes and 2 weeks or more after the notification the notified firm distributes a laboratory supply to the customer. For purposes of paragraph (15), if the distributor is temporarily unable to access the list of persons referred to under section 310(e)(1)(B)(v) [21 U.S.C. § 830(e)(1)(B)(v)], the distributor may rely on a written, faxed, or electronic copy of a certificate of self-certification submitted by the regulated seller or regulated person, provided the distributor confirms within 7 business days of the distribution that such regulated seller or regulated person is on the list referred to under section 310(e)(1)(B)(v) [21 U.S.C. § 830(e)(1)(B)(v)].

(b) Manufacture. It shall be unlawful for any person who is a registrant to manufacture a controlled substance in schedule I or II, or ephedrine, pseudoephedrine, or phenylpropanolamine or any of the salts, optical isomers, or salts of optical isomers of such chemical, which is—

(1) not expressly authorized by his registration and by a quota assigned to him pursuant to section 306 [21 U.S.C. § 826]; or

(2) in excess of a quota assigned to him pursuant to section 306 [21 U.S.C. § 826].

(c) Penalties.

(1)

(A) Except as provided in subparagraph (B), (C), or (D) of this paragraph and paragraph (2), any person who violates this section shall, with respect to any such violation, be subject to a civil penalty of not more than $ 25,000. The district courts of the United States (or, where there is no such court in the case of any territory or possession of the United States, then the court in such territory or possession having the jurisdiction of a district court of the United States in cases arising under the Constitution and laws of the United States) shall have jurisdiction in accordance with section 1355 of title 28 of the United States Code [28 U.S.C. § 1355] to enforce this paragraph.

(B)

(i) Except as provided in clause (ii), in the case of a violation of paragraph (5), (10), or (17) of subsection (a), the civil penalty shall not exceed $ 10,000.

(ii) In the case of a violation described in clause (i) committed by a registered manufacturer or distributor of opioids and related to the reporting of suspicious orders for opioids, failing to maintain effective controls against diversion of opioids, or failing to review the most recent information made available by the Attorney General in accordance with

section 307(f) [21 U.S.C. § 827(f)], the penalty shall not exceed $ 100,000.

(C) In the case of a violation of paragraph (16) of subsection (a) of this section by an importer, exporter, manufacturer, or distributor (other than as provided in subparagraph (D)), up to $ 500,000 per violation. For purposes of this subparagraph, a violation is defined as each instance of importation, exportation, manufacturing, distribution, or possession with intent to manufacture or distribute, in violation of paragraph (16) of subsection (a).

(D) In the case of a distribution, dispensing, or possession with intent to distribute or dispense in violation of paragraph (16) of subsection (a) of this section at the retail level, up to $ 1000 per violation. For purposes of this paragraph, the term "at the retail level" refers to products sold, or held for sale, directly to the consumer for personal use. Each package, container or other separate unit containing an anabolic steroid that is distributed, dispensed, or possessed with intent to distribute or dispense at the retail level in violation of such paragraph (16) of subsection (a) shall be considered a separate violation.

(2)

(A) If a violation of this section is prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was so committed, such person shall, except as otherwise provided in sub-

paragraph (B) or (D) of this paragraph, be sentenced to imprisonment of not more than one year or a fine under title 18, United States Code, or both.

(B) If a violation referred to in subparagraph (A) was committed after one or more prior convictions of the offender for an offense punishable under this paragraph (2), or for a crime under any other provision of this title or title III or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 2 years, a fine under title 18, United States Code, or both.

(C) In addition to the penalties set forth elsewhere in this title or title III, any business that violates paragraph (11) of subsection (a) shall, with respect to the first such violation, be subject to a civil penalty of not more than $ 250,000, but shall not be subject to criminal penalties under this section, and shall, for any succeeding violation, be subject to a civil fine of not more than $ 250,000 or double the last previously imposed penalty, whichever is greater.

(D) In the case of a violation described in subparagraph (A) that was a violation of paragraph (5), (10), or (17) of subsection (a) committed by a registered manufacturer or distributor of opioids that relates to the reporting of suspicious orders for opioids, failing to maintain effective controls against diversion

of opioids, or failing to review the most recent information made available by the Attorney General in accordance with section 307(f) [21 U.S.C. § 827(f)], the criminal fine under title 18, United States Code, shall not exceed $ 500,000.

(3) Except under the conditions specified in paragraph (2) of this subsection, a violation of this section does not constitute a crime, and a judgment for the United States and imposition of a civil penalty pursuant to paragraph (1) shall not give rise to any disability or legal disadvantage based on conviction for a criminal offense.

(4)

(A) If a regulated seller, or a distributor required to submit reports under section 310(b)(3) [21 U.S.C. § 830(b)(3)], violates paragraph (12) of subsection (a) of this section, or if a regulated seller violates paragraph (13) of such subsection, the Attorney General may by order prohibit such seller or distributor (as the case may be) from selling any scheduled listed chemical product. Any sale of such a product in violation of such an order is subject to the same penalties as apply under paragraph (2).

(B) An order under subparagraph (A) may be imposed only through the same procedures as apply under section 304(c) [21 U.S.C. § 824(c)] for an order to show cause.

REGULATORY PROVISIONS

21 C.F.R. § 1304.04—
Maintenance of Records and Inventories

(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, every inventory and other records required to be kept under this part must be keptby the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration.

(1) Financial and shipping records (such as invoices and packing slips but not executed order forms subject to §§ 1305.17 and 1305.27 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the Administration in the area in which the registrant is located. Unless the registrant is informed by the Special Agent in Charge that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge. All notifications must include the following:

(i) The nature of the records to be kept centrally.

(ii) The exact location where the records will be kept.

(iii) The name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally.

(iv) Whether central records will be maintained in a manual, or computer readable, form.

(2) A registered retail pharmacy that possesses additional registrations for automated dispensing systems at long term care facilities may keep all records required by this part for those additional registered sites at the retail pharmacy or other approved central location.

(3) A collector that is authorized to maintain a collection receptacle at a long-term care facility shall keep all records required by this part relating to those collection receptacles at the registered location, or other approved central location.

(b) All registrants that are authorized to maintain a central recordkeeping system under paragraph (a) of this section shall be subject to the following conditions:

(1) The records to be maintained at the central record location shall not include executed order forms and inventories, which shall be maintained at each registered location.

(2) If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records. If any code system is used (other than pricing information), a key to the code shall be provided to make the records understandable.

(3) The registrant agrees to deliver all or any part of such records to the registered location within two business days upon receipt of a written request from the Administration for such records, and if the Administration chooses to do so in lieu

of requiring delivery of such records to the registered location, to allow authorized employees of the Administration to inspect such records at the central location upon request by such employees without a warrant of any kind.

(4) In the event that a registrant fails to comply with these conditions, the Special Agent in Charge may cancel such central recordkeeping authorization, and all other central recordkeeping authorizations held by the registrant without a hearing or other procedures. In the event of a cancellation of central recordkeeping authorizations under this paragraph the registrant shall, within the time specified by the Special Agent in Charge, comply with the requirements of this section that all records be kept at the registered location.

(c) Registrants need not notify the Special Agent in Charge or obtain central recordkeeping approval in order to maintain records on an in-house computer system.

(d) ARCOS participants who desire authorization to report from other than their registered locations must obtain a separate central reporting identifier. Request for central reporting identifiers will be submitted to the ARCOS Unit. *See* the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(e) All central recordkeeping permits previously issued by the Administration expired September 30, 1980.

(f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances

as follows:

(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

(g) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in paragraph (f) of this section.

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy.

(2) Paper prescriptions for Schedule II controlled substances shall be maintained at the registered location in a separate prescription file.

(3) Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy.

(4) Paper prescriptions for Schedules III, IV, and V controlled substances shall be maintained at

the registered location either in a separate prescription file for Schedules III, IV, and V controlled substances only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1-inch-high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances. However, if a pharmacy employs a computer application for prescriptions that permits identification by prescription number and retrieval of original documents by prescriber name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

(5) Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of part 1311 of this chapter. The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by the Administration or other law enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.

21 C.F.R. § 1304.11—Inventory Requirements

(a) General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

(b) Initial inventory date. Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no

controlled substances on hand, he/she shall record this fact as the initial inventory.

(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

(d) Inventory date for newly controlled substances. On the effective date of a rule by the Administrator pursuant to §§ 1308.45, 1308.46, or 1308.47 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section.

(e) Inventories of manufacturers, distributors, registrants that reverse distribute, importers, exporters, chemical analysts, dispensers, researchers, and collectors. Each person registered or authorized (by §§ 1301.13, 1307.11, 1307.13, or part 1317 of this chapter) to manufacture, distribute, reverse distribute, dispense, import, export, conduct research or chemical analysis with controlled substances, or collect controlled substances from ultimate users, and required to keep records pursuant to § 1304.03 shall include in the inventory the information listed below.

(1) Inventories of manufacturers. Each person registered or authorized to manufacture controlled substances shall include the following information in the inventory:

(i) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form, the inventory shall include:

(A) The name of the substance and

(B) The total quantity of the substance to the nearest metric unit weight consistent with unit size.

(ii) For each controlled substance in the process of manufacture on the inventory date, the inventory shall include:

(A) The name of the substance;

(B) The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and

(C) The physical form which the substance is to take upon completion of the manufacturing process (*e.g.*, granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (*e.g.*, 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number or volume thereof.

(iii) For each controlled substance in finished form the inventory shall include:

(A) The name of the substance;

(B) Each finished form of the substance (*e.g.*, 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(C) The number of units or volume of each finished form in each commercial container (*e.g.*, 100-tablet bottle or 3-milliliter vial); and

(D) The number of commercial containers of each such finished form (*e.g.*, four 100-tablet bottles or six 3-milliliter vials).

(iv) For each controlled substance not included in paragraphs (e)(1) (i), (ii) or (iii) of this section (*e.g.*, damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:

(A) The name of the substance;

(B) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(C) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

(2) Inventories of distributors. Each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.

(3) Inventories of registrants that reverse distribute. Each person registered or authorized to reverse distribute controlled substances shall include in the inventory, the following information:

(i) The name of the substance, and

(ii) The total quantity of the substance:

(A) For controlled substances in bulk form, to the nearest metric unit weight consistent with unit size;

(B) For each controlled substance in finished form: Each finished form of the substance (*e.g.*, 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter); the number of units or volume of each finished form in each commercial container (*e.g.*, 100-tablet bottle or 3-milliliter vial); and the number of commercial containers of each such finished form (*e.g.*, four 100-tablet bottles or six 3-milliliter vials); and

(C) For controlled substances in a commercial container, carton, crate, drum, or other receptacle that has been opened: If the substance is listed in Schedule I or II, make an exact count or measure of the contents; or if the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents shall be made; or

(iii) For controlled substances acquired from collectors and law enforcement: The number and size (*e.g.*, five 10-gallon liners, etc.) of sealed inner liners on hand, or

(iv) For controlled substances acquired from law enforcement: the number of sealed mail-back packages on hand.

(4) Inventories of importers and exporters.

Each person registered or authorized to import or export controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section. Each such person who is also registered as a manufacturer or as a distributor shall include in his/her inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (*e.g.*, in transit or in storage for shipment).

(5) Inventories of chemical analysts. Each person registered or authorized to conduct chemical analysis with controlled substances shall include in his inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section as to substances which have been manufactured, imported, or received by such person. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than 20 grams of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. Laboratories of the Administration may possess up to 150 grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances. No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

(6) Inventories of dispensers and researchers. Each person registered or authorized to dispense or conduct research with controlled substances shall

include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container that has been opened, the dispenser or researcher shall do as follows:

(i) If the substance is listed in Schedules I or II, make an exact count or measure of the contents; or

(ii) If the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

(7) Inventories of collectors. Each registrant authorized to collect controlled substances from ultimate users shall include in the inventory the following information:

(i) For registrants authorized to collect through a mail-back program, the record shall include the following information about each unused mail-back package and each returned mail-back package on hand awaiting destruction:

(A) The date of the inventory;

(B) The number of mail-back packages; and

(C) The unique identification number of each package on hand, whether unused or awaiting destruction.

(ii) For registrants authorized to collect through a collection receptacle, the record shall include the following information about each unused

inner liner on hand and each sealed inner liner on hand awaiting destruction:

(A) The date of the inventory;

(B) The number and size of inner liners (*e.g.*, five 10-gallon liners, etc.);

21 C.F.R. § 1304.21—
General Requirements for Continuing Records

(a) Every registrant required to keep records pursuant to § 1304.03 shall maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, and each inner liner, sealed inner liner, and unused and returned mail-back package, except that no registrant shall be required to maintain a perpetual inventory.

(b) Separate records shall be maintained by a registrant for each registered location except as provided in § 1304.04 (a). In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(c) Separate records shall be maintained by a registrant for each independent activity and collection activity for which he/she is registered or authorized, except as provided in § 1304.22(d).

(d) In recording dates of receipt, distribution, other transfers, or destruction, the date on which the controlled substances are actually received, distributed, otherwise transferred, or destroyed will be used as the date of receipt, distribution, transfer, or destruction (*e.g.*, invoices or packing slips, or DEA Form 41). In

maintaining records concerning imports and exports, the registrant must record the anticipated date of release by a customs official for permit applications and declarations and the date on which the controlled substances are released by a customs officer at the port of entry or port of export for return information.

(e) Record of destruction. In addition to any other recordkeeping requirements, any registered person that destroys a controlled substance pursuant to § 1317.95(d), or causes the destruction of a controlled substance pursuant to § 1317.95(c), shall maintain a record of destruction on a DEA Form 41. The records shall be complete and accurate, and include the name and signature of the two employees who witnessed the destruction. Except, destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (*e.g.*, some of the substance remains in a vial, tube, or syringe after administration but cannot or may not be further utilized), shall be properly recorded in accordance with § 1304.22(c), and such record need not be maintained on a DEA Form 41.

21 C.F.R. § 1306.04—Purpose of Issue of Prescription

(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. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legiti-

mate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. § 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in § 1301.28 of this chapter.

21 C.F.R. § 1306.21

(a) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V that is a prescription drug as determined under section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353(b)) only pursuant to either a paper prescription signed by a practitioner, a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, an electronic prescription that meets the requirements of this part and part 1311 of this chapter, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in § 1306.05, except for the signature of the practitioner.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule III, IV, or V in the course of his/her professional practice without a prescription, subject to § 1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III, IV, or V only pursuant to a paper prescription signed by an individual practitioner, a facsimile of a paper prescription or order for medication transmitted by the practitioner or the practitioner's agent to the institutional practitioner-pharmacist, an electronic prescription that meets the requirements of this part and part 1311 of this chapter, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in § 1306.05 except for the signature of the individual practitioner), or pursuant to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user, subject to § 1306.07.

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