UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
GAINESVILLE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. Dr. WILLIAM GREENE, Defendant.	CIVIL ACTION NO. 2:17-cv-272-RWS

ORDER

This case is before the Court on Plaintiff the United States' Motion for Summary Judgment [56] on the issue of Defendant Dr. William Greene's liability for recordkeeping violations under the Controlled Substances Act, 21 U.S.C. § 842(a)(5). The Court has reviewed the record, and, for the reasons below, the Government's Motion is **GRANTED in part** and **DENIED in part**.

Background

1. Dr. Greene's Practice

Defendant Dr. William Greene is a medical doctor whose entire practice involves performing a unique surgery to restore fertility to women who previously had their fallopian tubes tied. During surgery, a nurse anesthetist in Greene's office

uses Fentanyl, a controlled substance, to place the patient under anesthesia and manage her pain. [Plaintiff's Statement of Material Facts, Dkt. 56-2, at ¶ 11]. After the surgery is over, Dr. Greene (or one of his staff) gives the patient a bottle of 10 pills of 7.5mg of Hydrocodone, also a controlled substance, to manage her pain at home. [Id. at ¶ 13]. His office dispenses the pills directly, rather than writing a prescription, because he offers the entire service—surgery plus medicine—as a fixed cost package. [Greene Deposition at 29:4–9]. During the two-year period relevant here, Dr. Greene performed approximately 300 of these surgeries. [Id. at 108:14–17].

2. Reported Theft of Controlled Substances

In late 2016, Dr. Greene filed a police report alleging that his longtime employee Sharon Stewart had diverted Hydrocodone pills by forging his signature on order forms and stealing the pills when they were delivered to the office.

Dr. Greene's practice had a long-established process for ordering the controlled substances, much of which was delegated to Sharon Stewart. [Plaintiff's Facts, at ¶¶ 35, 37]. She mailed the completed order forms. She received the drugs and put them in the safe. And she reviewed the invoices from the suppliers before turning them over to Nicole Mixon, the bookkeeper for the practice. Sometimes,

Stewart had altered the invoices—changing the 10mg to 7.5mg, claiming that it was a mistake. [Defendant's Statement of Material Facts, Dkt. 63-2, at ¶ 2].

In 2016, however, Mixon began to be suspicious of Stewart. The first red flag was when Stewart purchased four new cars in a short stretch. [Mixon Deposition at 102–04]. The next was when Stewart, while Mixon was on vacation, changed how one of the drug suppliers was paid to direct deposit, so that invoices would not be sent and reviewed in the same way. [Id. at 104–05]. At one point, to investigate her suspicions, Mixon requested the statements directly from the supplier. [Id. at 156]. When she received them, the invoices showed orders for thousands of Hydrocodone pills. Mixon showed the invoices to Dr. Greene. He fired Stewart soon after the discovery and reported the theft to law enforcement.

3. The DEA Investigation

The local police notified the DEA. Upon receiving the complaint, the DEA, led by Investigator Jason Allen, opened its own investigation. It began by reviewing the ordering history associated with Dr. Greene's DEA registrant number. The history showed a significant increase in the quantity of Hydrocodone pills ordered beginning in 2014. [Allen Report of Investigation, Dkt. 56-3-1, at ¶ 2]. Consistent with Dr. Greene's complaint, there were orders for 10mg pills in addition to 7.5mg pills. [Id.] Still, the DEA had concerns about Dr. Greene because

it doubted that the purported diversions, which stretched back three years, could have all taken place without his knowledge.

So, the DEA continued to investigate Dr. Greene, even despite his complaint about Stewart's alleged theft. Two weeks after Dr. Greene filed the criminal report, the DEA conducted an unannounced inspection and accountability audit of his practice. The investigators sought to determine if his records could account for the number of pills shown in the ordering history.

4. Dr. Greene's Alleged Recordkeeping Deficiencies

The DEA concluded that Greene's records were deficient, in three ways: first, Dr. Greene was unable to produce a record of his inventory of drugs, which the Controlled Substances Act required him to maintain. See 21 U.S.C. § 827(b).

Second, Greene was mostly unable to produce purchase order forms, called DEA Forms 222, which he was also required to maintain. See 21 U.S.C. § 827(a)(3); 21 C.F.R. §§ 1305.03, 1305.13. For the forms he did have that covered the relevant timeframe, Dr. Greene told the DEA that all but one were forged by Stewart.[1] [Plaintiff's Facts at ¶ 56]. And the one he acknowledged

[1] At this stage, the Government does not dispute that the signatures were forged.

having signed was incomplete, lacking a notation required to show the drugs had been received.

Third, the DEA found that he did not have appropriate records documenting his dispensing of the drugs, which he again was required to maintain. See 21 U.S.C. § 827(a)(3); 21 C.F.R. § 1304.22. There were of course no dispensing records of the 10mg pills, because the practice never used them. There were dispensing records of the 7.5mg pills and the fentanyl, but the DEA found these to be deficient, for different reasons: for the 7.5mg pills, the dispensing records—again, perhaps consistent with the allegations of diversion—could not account for a substantial portion of the pills ordered. And for the fentanyl, the DEA found the records to be inadequate because the logbook entries were handwritten and illegible, such that Investigator Allen could not complete his audit. [Id. at ¶ 80].

5. The Current Case

In light of the purported deficiencies, the Government initiated this civil suit. It alleged that Dr. Greene negligently failed to "make, keep, or furnish" records required under the CSA. See 21 U.S.C. § 842(a)(5). The parties have concluded discovery, and the Government now moves for summary judgment on the issue of Dr. Greene's liability for all three categories of records.

Discussion

I. Legal Standard: Motion for Summary Judgment

Federal Rule of Civil Procedure 56 requires that summary judgment be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."

"The moving party bears 'the initial responsibility of informing the . . . court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact.'" Hickson Corp. v. N. Crossarm Co., 357 F.3d 1256, 1259 (11th Cir. 2004) (quoting Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986)). Where the moving party makes such a showing, the burden shifts to the non-movant, who must go beyond the pleadings and present affirmative evidence to show that a genuine issue of material fact does exist. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 257 (1986).

An issue is genuine when the evidence is such that a reasonable jury could return a verdict for the non-moving party. Id. at 249-50. A fact is material if a dispute over that fact would affect the outcome of the suit under the governing law. Id. at 248. The applicable substantive law identifies which facts are material. Id.

In resolving a motion for summary judgment, the court must view all evidence and draw all reasonable inferences in the light most favorable to the non-moving party. Patton v. Triad Guar. Ins. Corp., 277 F.3d 1294, 1296 (11th Cir. 2002). But the court is bound only to draw those inferences that are reasonable. "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial." Allen v. Tyson Foods, Inc., 121 F.3d 642, 646 (11th Cir. 1997) (quoting Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986)). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." Anderson, 477 U.S. at 249–50 (internal citations omitted); see also Matsushita, 475 U.S. at 586 (once the moving party has met its burden under Rule 56(a), the nonmoving party "must do more than simply show there is some metaphysical doubt as to the material facts").

II. CSA Recordkeeping Statutory Framework

Here, the governing substantive law centers on the recordkeeping requirements under the Controlled Substances Act. See 21 § U.S.C. 801 *et seq*.

A. Section 827: Specific Recordkeeping Requirements

Dispensers of controlled substances must track the drugs they dispense. In particular, under 21 U.S.C. § 827, any registrant who dispenses controlled substances must maintain "a complete and accurate record" of:

- "all stocks . . . on hand," as measured every two years. § 827(a)(1);
- "each substance . . . received." § 827(a)(3); and
- "each substance . . . sold, delivered, or otherwise disposed of." Id.

The purpose, of course, is to allow for the DEA to be able to review the records and track all the substances. The biennial inventory under § 827(a)(1) provides a baseline, and the ongoing records under § 827(a)(3) show substances moving in and out. All of these records must be maintained separately from other records, must be "readily retrievable," and must be kept for two years. § 827(b). The records must also comply with any regulations promulgated by the Attorney General. Id.

In particular, regulations require that a registrant use a specific order form, called a DEA Form 222, to order controlled substances. 21 C.F.R. § 1305.03. The purchaser initially fills out and signs the form, which has three color-coded copies. 21 C.F.R. § 1305.13. He sends the top two copies to the supplier and retains the third for himself. Id. The supplier fills out the date and details of when the order was filled, sends a copy to the DEA, and retains a copy for itself. Id. The

purchaser, upon receipt of the drugs, notates the date and details of the orders received. Id. Thus, the DEA, supplier, and purchaser should all have copies of the same order form.

Similarly, the regulations require that, when dispensing controlled substances to a user, the registrant record the quantity and type of drug dispensed as well as information about the person to whom the drug was dispensed. 21 C.F.R. § 1304.22(c). Here, the registrant is not required to use any particular form.

B. Section 842(a)(5): Penalty for Negligent Failure

Under 21 U.S.C. § 842(a)(5), it is unlawful for any person to "negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information" required by the CSA,[2] such as those described above. Negligence is a key issue here, because, for some of the claims, there is no question that Dr. Greene failed to keep and produce the records; the only question is whether he did so negligently.

Negligence means "the failure to exercise the standard of care that a reasonably prudent person would have exercised in a similar situation." United

[2] It is also unlawful to "refuse" to do so, but there is no evidence of refusal here. The Motion turns only on the "negligently fail" prong.

States v. Pruett, 681 F.3d 232, 242 (5th Cir. 2012) (citing Black's Law Dictionary 1061 (8th ed. 2004)). It is true that no court appears to have directly addressed the standard for negligence under § 842. United States v. Al-Amin, 2016 WL 744306, at *4 (reviewing cases and noting that none "sheds light on what constitutes a negligent failure to record"). But courts have routinely held that other statutory penalty provisions which include the word "negligence" invoke the word's ordinary meaning. E.g., United States v. Pruett, 681 F.3d 232, 242 (5th Cir. 2012).

Negligence is particularly relevant to a summary judgment determination because negligence is, generally speaking, a question of fact for the jury to decide. E.g., StopLoss Specialists, LLC v. VeriClaim, Inc., 340 F. Supp. 3d 1334, 1355 (N.D. Ga. 2018) (citing Braun v. Soldier of Fortune Magazine, Inc., 968 F.2d 1110, 1114 (11th Cir. 1992)). That is equally true under § 842(a)(5) as with traditional negligence claims. See United States v. United Pain Care, Ltd., 747 F. App'x 439, 440 (8th Cir. 2019) (jury verdict of negligence). Still, as the Government correctly points out, courts have granted summary judgment on liability under this provision and in other contexts involving negligence. E.g., United States v. Heim, 2014 WL 245357, at *4 (N.D. Ohio Jan. 22, 2014).

With these principles in mind, the Court turns to the claims at issue here.

III. Analysis

The Government has challenged Dr. Greene's recordkeeping on three different grounds, which correspond to the three different requirements discussed above. First, the Government claims that Greene failed to keep a record of the biennial inventory. Second, it claims that he failed to make or keep proper DEA Forms 222 for the purchase of controlled substances. And third, it claims that he failed to make proper records of the controlled substances he dispensed. Each of these claims rests on different legal footing. They are addressed in turn below.

A. Biennial Inventory

Under § 827 of the CSA, Dr. Greene was required to conduct a biennial inventory and maintain a "readily retrievable" record of the results. See 21 U.S.C. § 827(a)(1), (b). There is no dispute that he failed to produce the record. The question is whether his failure was negligent. The Court finds that it was.

In his deposition, Dr. Greene admitted that the report was simply lost—"garden variety lost," as he put it. [Greene Dep. at 155:16–24]. Later, in his affidavit, he attempts to assert that Sharon Stewart may have stolen the record to cover her tracks, but he has no personal knowledge of his assertion—it amounts to mere speculation, and the Court does not consider it as evidence. See F.R.C.P

56(c)(4). Thus, the Court finds that the record shows without a dispute that the report was lost.

Further, Greene admitted that he knew he was required to maintain the record and that he directed the inventory process, including determining where the record should be stored. [Id. at 67:3–8; 152:11–19]. He directly instructed his subordinate to complete it, and he took responsibility to maintain the record. [Id. at 151:5–6]. Therefore, the Court finds that there is no genuine dispute of material fact as to his involvement in the process, such that the loss constitutes his negligent failure to keep the record.

Accordingly, the Government's Motion for Summary Judgment on the claim concerning the biennial inventory is **GRANTED**.

B. DEA Forms 222

Under 21 C.F.R. §§ 1305.03, 1305.13, Greene was required to use and keep the DEA Forms 222 for each order of controlled substance. The Government claims he negligently failed to make and keep these records. However, unlike the clear record for the claim above, this claim includes factual uncertainties that defeat the Government's Motion.

There is no dispute that the forms produced by Dr. Greene did not account for all the orders placed to suppliers. But Greene's key defense centers on Sharon

Stewart: that he had delegated to her much of the process for handling the forms, especially after he signed them; that she forged or altered some of the forms he discovered; and that she may well have destroyed or stolen others.

A quick summary of the specific DEA Forms 222 at issue—the record shows two types of forms: (1) the purchaser copies produced by Dr. Greene during the DEA inspection [Dkt. 56-3-2, 56-3-3], and (2) the supplier copies obtained by the DEA from a supplier to Greene's practice. [Dkt. 56-3-4].

As for the purchaser forms: during the inspection, Greene produced all the purchaser copies he could find in his office. He presented them to the DEA in two stacks: (a) those he claimed to have signed himself [Dkt. 56-3-2], and (b) those he claimed were forged by Sharon Stewart [Dkt. 56-3-3].[3] Importantly, the Government accepts for purposes of this Motion Dr. Greene's claims of forgery. The Court, viewing the evidence in the light most favorable to Greene, does the same. Between the two stacks, there are 13 forms that fall within the relevant

[3] For one of these forms [Dkt. 56-3-3 at 43], it is unclear whether Dr. Greene maintains that it was forged or acknowledges that he signed it. He appears to contradict himself in his Response, which he filed *pro se*. [Compare Defendant's Response, Dkt. 63 at ¶ IV(a), with ¶ IV(d)]. The Government in its Reply credited Greene's acknowledgement, but the Court believes the safer approach, given the posture of this Motion, is to credit his denial and continue to consider the form as a forgery.

timeframe—12 forgeries and 1 signed by Dr. Greene. The rest are either illegible or dated from an earlier time.

In addition to the forms Dr. Greene produced, the DEA received forms from one of the suppliers used by the practice.[4] The supplier produced 22 forms that covered the relevant time frame. Notably, based on the Court's review, only 3 of these 22 supplier forms appear to match to the purchaser forms produced by Greene—2 match forged forms; another matches the single form Greene signed.

How to analyze the legal effects of the presence or absence of these forms depends on the theory of liability. The Government presents three possible theories. Each is addressed below.

Theory 1. Defective Forms

The first theory centers on the 13 forms that Dr. Greene actually produced within the timeframe. The Government says these are defective because they lacked a required notation about the date and amount of drugs received that was required to be added to the form upon receipt of the order. See 21 C.F.R.

[4] The record is unclear about why the DEA did not include supplier forms from the other suppliers, given that the total quantity from the requested supplier did not account for the entire quantity of pills that appeared in the DEA's ordering history.

§ 1305.13(e). Under this theory, Greene would be liable for 13 violations of § 842(a)(5)—one violation for each defective form.

While this theory might support liability for legitimate forms, the problem is that most of the forms produced are not legitimate. For the forged forms, it cannot be said that Dr. Greene in fact purchased those controlled substances because, even assuming the orders were placed and filled,[5] the ordering was performed illegally by someone else not authorized to do so. The faulty notation is irrelevant because the forms were never legitimate to begin with. Therefore, Greene could only be held liable, if at all, for the initial forgeries, not merely for the lack of a notation.

Whether Greene can be held liable for the initial forgeries requires a factual determination. Under the statute, Greene is only liable if he "negligently failed" to make the records. There is no dispute here that Stewart forged the records. The question is whether Stewart's forging equates to Greene's negligent failure. This is a question of proximate cause. And it is a question of fact. The ultimate answer

[5] Dr. Greene argues that the Government has failed to produce corresponding supplier forms showing that the forged purchaser copies actually reflected real orders. As mentioned, 2 of the 12 matched to supplier forms obtained by the DEA. Further, the DEA's order history shows a large number of orders. Therefore, there is evidence that tends to show the orders were in fact placed.

need not be resolved here; the issue, however precludes summary judgment under this theory on those 12 forged forms.

That leaves the one form that Greene did sign. But this one also faces a negligence hurdle. Whether Greene negligently failed to notate the form does not automatically follow from the fact that it was not notated—that would be strict liability. The lack of a notation must be linked to his conduct.

It is not enough to say that he did himself make the notation. Though he is ultimately responsible, the regulations do not necessarily require that Greene *individually* make the notation. Compare § 1305.12 ("Each DEA Form 222 must be signed and dated by a person authorized to sign an application for registration"), with § 1305.13(e) (referring only to the "purchaser"). So, the question here is whether Stewart's failure to notate the forms—as a legitimate part of her authorized duties—constitutes Greene's negligent failure.[6]

This question involves a factual determination for the jury. The evidence shows that Greene believed he trained Stewart on how to fill out the form. [Greene Dep. at 89:13–15]. He stated that he likely trained her on how to fill out the form when the drugs were received. [Id. at 89:21–90:2]. Greene further explained to her

[6] The parties have not argued for any sort of vicarious liability, and so the Court does not address the question of whether vicarious liability could arise under § 842(a)(5).

the importance of filling out the form. [Id. at 91:13–18]. Construing the evidence in the light most favorable to Dr. Greene, that is enough to raise a jury question about his negligence. Accordingly, the Government cannot prevail at this stage under this theory.

Theory 2. Greene Should Have Known Better

The second and third theories focus instead on the *absence* of DEA Forms 222. It is undisputed that, for the time period at issue, Greene produced only one form that he acknowledged as having signed. The Government notes correctly that the production permits one of two inferences: either Greene in fact signed only one form during the two-year period—i.e., the single form that was produced—or he signed others which have now been lost. In his deposition, Greene seemed to waver on this point—he could not recall whether he signed only the one, but he stated that that there *could* be other forms that he signed that were lost or taken by Stewart. [Id. at 136:7–8]. He later argued there were almost certainly other forms that he signed. [Defendant's Response, Dkt. 63 at ¶ IV(f)].

The two remaining theories correspond to these two possible interpretations. The Court considers each theory in turn. Ultimately, neither warrants granting the Government's Motion.

Assuming that Dr. Greene signed only one form during the time, the Government argues that he *must* have known that something was amiss when he went for months at a time without signing a form. Given that he was on notice, his failure to do anything, according to the Government, constitutes negligence.

To support this theory, the Government relies on three basic factual assertions. The first assertion is undisputed; the second two are contradicted at least in part by some of Greene's evidence. First, it is undisputed that Greene knew both that he was routinely dispensing the substances and that he knew he had to sign the form to order them.

Next, the Government asserts that Greene reviewed and approved all invoices. The implication of this assertion is that Greene would have seen the higher charges from the supplier. While Greene did not directly dispute that he carefully reviewed the invoices, he did note that it was Stewart's responsibility to review the invoices and identify any discrepancies, and that he trusted her to do so. [Greene Affidavit, Dkt. 64-4, at ¶ 15]. Further, he introduced evidence showing that she altered invoices and attempted to change the payment from invoices to direct deposits. [Id. at ¶ 36].

Finally, the Government asserts that Stewart could have obtained the blank Forms 222 only by asking the Defendant to provide them from a locked safe. The

implication is that Greene must have given her the blank forms. And if Greene only signed the one, he should have wondered what became of those that he never saw again. But Dr. Greene disputed this theory by introducing some evidence tending to show that Stewart could have gone around him to obtain the forms. [Defendant's Facts, Dkt. 63-2, at ¶¶6–7].

Construing these facts most favorably to Dr. Greene does not permit a finding of negligence as a matter of law. Even the undisputed factual assertion does not inexorably lead to the Government's conclusion. The single form that Greene acknowledged signing contained an order for 13 bottles of pills, which was 4-6 times the typical monthly amount ordered. [Dkt. 56-3-2 at 24]. When questioned about this, Greene couldn't explain why that one form was higher. [Allen Report, Dkt. 56-3-1, at ¶ 14]. But the larger order cuts against the thrust of the Government's claim—that his sole signature would not account for the large, ongoing quantity the office needed.

Even assuming Dr. Greene signed only one form over the interval period, whether he negligently failed to make and keep the records is a factual issue for the jury. Therefore, the Government cannot prevail on this theory of liability.

Theory 3. The Disappearing Forms

The basic assumption of the third theory is that Dr. Greene signed other forms over the two-year period, but those forms were subsequently lost. The Government contends that the loss constitutes a negligent failure to keep the records, much like with the biennial inventory discussed above. But these missing records differ from the missing biennial inventory in a few key respects.

First, there is little evidence that Dr. Greene ever actually created them. This theory is based on speculation. If the Government could establish that he in fact signed other orders—whether through testimony or by providing supplier forms signed by Dr. Greene[7]—and then failed to retain the purchaser copies, it would clear this hurdle. But that is not the case.

Next, even if the Government had showed that he signed other forms that were absent, it would have to establish that the loss was a result of his negligence. Unlike with the biennial inventory, where Greene directed the process and was aware of where the file *should* be stored, for the purchaser copies of the DEA

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[7] It is unclear whether the Government asserts that Greene in fact signed the 22 supplier forms obtained by the DEA which did not match to the forms he produced. Given, however, that all those orders (except the matching one) included orders for 10mg of Hydrocodone, which the practice did not dispense, the safer assumption for these purposes is that those forms were also forged.

Forms 222, he delegated the task almost entirely to Stewart. The evidence showed that he did not even know where she stored them because he fully relied on her to handle the process since the time that he trained her at the beginning of her employment. [Greene Dep. at 95:18–22; 105:24 –106:7].

This means that the records' disappearance falls to her. Either she negligently failed to keep them as a duly authorized employee, or she intentionally failed to keep them, acting outside the scope of her duties. Either way, the question of whether her failure proves that Dr. Greene negligently failed to keep the records is a question of fact that the jury would have to decide. So the Government cannot prevail on this theory either.

* * *

There is no dispute that Dr. Greene failed to keep and produce the requisite forms. Further, the recordkeeping failure appears to have allowed for exactly the sort of diversion the requirements are intended to prevent. Thus, it may well be that, at trial, Dr. Greene would be found negligent. But the same cannot be said as a matter of law under any of the theories set forth by the Government.

Accordingly, the Government's Motion for Summary Judgment as to Dr. Greene's negligent failure to make and keep the proper DEA Forms 222 in accordance with 21 C.F.R. §§ 1305.03, 1303.13 is **DENIED**.

C. Dispensing Records

Under 21 C.F.R. § 1304.22, someone who dispenses controlled substances must maintain records with information about the substances and the person to whom they were dispensed. The Government argues that the evidence shows that Dr. Greene negligently failed to maintain dispensing records for all three types of controlled substance: Hydrocodone 10mg, Hydrocodone 7.5mg, and Fentanyl. The Court disagrees.

1. Hydrocodone 10mg

The Government asserts that Dr. Greene should be liable for negligently failing to maintain a dispensing record for every Hydrocodone 10mg pill which was allegedly ordered because the entire quantity constitutes a "shortage" under the DEA's calculation. But the Government misses the mark.

There is no evidence that Dr. Greene ever dispensed any of the 10 mg pills. Indeed, all the evidence shows that he did not dispense them. To the extent that any evidence shows the practice (beyond Sharon Stewart) ever even received the 10mg pills, there arises a genuine factual dispute, because Dr. Greene claims otherwise. Therefore, he cannot be deemed liable as a matter of law for failing to maintain records of the dispensing of these drugs.

2. Hydrocodone 7.5mg

A similar problem plagues the Government's argument about the 7.5mg pills. The Government does not argue that the records were inaccurate in how they documented those pills that were in fact dispensed. Greene produced evidence to support the practice's recordkeeping for dispensing to patients, including an affidavit from Melissa Wills [Dkt. 63-5], the logbooks themselves [Dkt. 63-6], and a count of the exact number of pills he dispensed. [Dkt. 63-7]. Further, the DEA appears to have credited those records in computing its totals. [Dkt. 56-3-5].

Instead, the Government contends that the records were faulty because they failed to account for the total quantity of pills allegedly ordered. This is the same argument as above, and it fails for the same reason. Because there is no evidence that the excess 7.5mg pills were dispensed to patients; there can be no finding as a matter of law that Dr. Greene negligently failed to maintain dispensing records.

3. Fentanyl

The argument for Fentanyl differs. Here, the DEA acknowledged that the practice maintained a logbook, but determined that the entries were not sufficient or sufficiently clear for its investigators to complete its audit. Part of the difficulty with the DEA's calculation was the lack of a biennial inventory and a lack of a current count of the drug. Other difficulties included crossed out labels and

illegible handwriting. To counter, Greene referred to the same evidence describing the recordkeeping practice. [Dkt. 63-5]. And again he produced a count of the amount of Fentanyl used. [Dkt. 63-7].

The Government's argument essentially boils down to this: because the DEA was unable to successfully complete its calculation, therefore, the records must have been deficient, and therefore, Dr. Greene must have violated § 842(a)(5). But that argument falls short.

First, while the statute requires that the records be "in such form that the information sought by [the DEA] is readily retrievable," 21 U.S.C. §827(b), the Government has not pointed to any part of the statute or the regulation that holds a dispenser liable for the DEA's inability to complete an audit. To warrant summary judgment, the evidence must show that Dr. Greene negligently failed to maintain the records required by § 1304.22. The DEA's own failure to interpret those records does not establish a per se violation of § 842(a)(5).

Further, the DEA's inability to complete the audit here was based on records *besides* the dispensing records. A simple analogy illustrates the problem: if the DEA sought to calculate A+B=C, and the registrant failed to provide information sufficient to determine A, of course the DEA would not be able to balance the overall equation; but, it does *not* automatically follow that the registrant would

have also failed to produce information sufficient to determine B. That Greene failed to produce the inventory does not dictate whether the dispensing records were themselves invalid. The only issue is whether the records themselves sufficiently documented the dispensing, as required by the regulation.

And that issue, as it happens, involves a genuine factual dispute. Even crediting the many shortcomings in the logbook highlighted by Investigator Allen, Greene's evidence showed that his employee was able to interpret the logbook and determine the amount of fentanyl dispensed. Although this evidence is not as convincing as the logbook for the Hydrocodone 7.5mg pills, still it suffices here. Construing the evidence in the light most favorably to Greene, it cannot be said that he failed to maintain the proper records as a matter of law.

* * *

For the reasons above, the Government's Motion for Summary Judgment as to Dr. Greene's negligent failure to make and keep the proper dispensing records in accordance with 21 C.F.R. § 1304.22 is **DENIED**.

Conclusion

For the foregoing reasons, the Government's Motion for Summary Judgment is **GRANTED in part** and **DENIED in part**. Dr. Greene is hereby adjudged **LIABLE** for the failure to keep a record of his biennial inventory. The case will

proceed to trial on the questions of liability for the DEA Forms 222 and the dispensing records.

SO ORDERED this 15th day of November, 2019.

RICHARD W. STORY
United States District Judge