IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *Plaintiff,* v. AMERISOURCE BERGEN CORPORATION, et al., *Defendants.*	CIVIL ACTION NO. 22-5209

MEMORANDUM

PAPPERT, J. **November 6, 2023**

AmerisourceBergen Corporation ("Amerisource") is one of the largest pharmaceutical distributors in the United States and one of the ten largest companies in the nation by revenue. (Compl. ¶¶ 63-64, ECF No. 1.) It sells pharmaceutical products, including controlled substances such as opioids, to chain and independent retail pharmacies across the country through a network of subsidiaries like AmerisourceBergen Drug Corporation ("ABDC") and Integrated Commercialization Solutions ("ICS"). (*Id.* ¶¶ 15-16, 65-66, 72-73, 77-78.)[1]

The Controlled Substances Act ("CSA") establishes a regulatory scheme governing the manufacture, distribution, dispensing and possession of certain drugs. The law seeks to prevent, among other things, the diversion and abuse of controlled substances. Of specific relevance to this case, Section 832(a)(3) of the CSA, and before

[1] Unless otherwise specified, the Court refers to the Defendants collectively as Amerisource. The Government alleges Amerisource exercised ultimate control over ICS and ABDC in relevant respects, such as by providing shared personnel and services, including its Corporate Security and Regulatory Affairs Department ("CSRA"). (*Id.* ¶¶ 17-19, 87-95.) The CSRA is allegedly administered under the authority of Amerisource's legal department and receives direction from its Board of Directors and Ethics Committee. (*Id.* ¶ 19.) ABDC and ICS also allegedly rely on Amerisource's executives and officers to serve ABDC and ICS in the same capacities. (*Id.* ¶ 20.)

the CSA was amended in 2018, an implementing regulation, Section 1301.74(b), require pharmaceutical distributors to identify "suspicious orders" from their customers and, when discovered, report these orders to the Drug Enforcement Administration. 21 U.S.C. § 832(a)(1), (3); 21 C.F.R. § 1301.74(b).

The United States alleges that from January 1, 2014 to the present, Amerisource violated the CSA by failing to report suspicious orders to the DEA, thereby contributing to the nation's burgeoning opioid crisis. (Compl. ¶¶ 80, 115-16, 504-05.) The Government seeks civil penalties for each alleged violation over that time frame. (*Id.* ¶¶ 504-06.) Amerisource moves to dismiss the Government's Complaint, arguing that the suspicious order reporting requirement is unconstitutionally vague, that it was not required to report the orders the Government says it was, and that it is not liable for any civil penalties for alleged conduct that occurred before the CSA was amended to codify the regulation's suspicious order reporting requirement. That amendment took effect on October 24, 2018.

After considering the parties' submissions and holding oral argument, the Court largely denies the motion, but grants it in part, concluding that the Government cannot state a claim for Amerisource's alleged failure to report suspicious orders preceding the CSA's amendment.

I

A

The Controlled Substances Act of 1970, 21 U.S.C. § 801 et seq., establishes a "comprehensive regime," with the objectives to "conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." *Gonzales v. Raich*, 545

U.S. 1, 12 (2005). In enacting the CSA, Congress was "particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels." *Id.* at 12-13. It was specifically aware that "registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic." *United States v. Moore*, 423 U.S. 122, 135 (1975).

To accomplish its goals, the CSA creates "a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Raich*, 525 U.S. at 13. The system is "closed" in that participants in all stages of these substances' manufacture and distribution are required to register with the DEA and follow the CSA and its implementing regulations. 21 U.S.C. §§ 822; 823.[2]

The CSA categorizes controlled substances into five schedules, grouping these drugs by their accepted medical uses, their psychological and physical effects on the body, and their potential for abuse. *Raich*, 545 U.S. at 13. Substances in Schedules II-V all exhibit varying degrees of potential for abuse and physical and psychological dependence. 21 U.S.C. § 812(b)(2)-(5).

Under the CSA, distributors are persons or entities that "deliver" controlled substances, meaning actually or constructively transferring these substances or attempting to transfer them. 21 U.S.C. § 802(8), (11). Like other participants in the controlled substance supply chain, distributors are required to register with the DEA. 21 U.S.C. § 823(b). Distributors cannot be registered, however, if the issuance of a such

[2] The CSA's provisions refer to the Attorney General rather than the DEA, but also authorize the Attorney General to "delegate any of his functions under this title to any officer or employee of the Department of Justice. 21 U.S.C. § 871(a). The Attorney General has delegated this authority to the DEA Administrator. 28 C.F.R. § 0.100(b).

a registration to a given distributor is "inconsistent with the public interest." 21 U.S.C. § 823(b), (f).

Whether registration is in the public interest depends, among other factors, on a distributor's maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels. 21 U.S.C. § 823(b)(1), (f)(1). Failure to maintain these controls is a basis for suspension or revocation of a distributor's registration. 21 U.S.C. § 824(a)(4). Revocation and suspension are effectuated through an administrative procedure that is "independent of, and not in lieu of, criminal prosecutions or other proceedings" under the CSA or any other federal laws. 21 U.S.C. § 824(c)(4).

The CSA also authorizes the DEA (through the Attorney General's delegation) to "promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals," and "and "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this title." 21 U.S.C. §§ 821, 871(b). One of these regulations requires distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," and to report suspicious orders "when discovered." 21 C.F.R. § 1301.74(b). Distributors enjoy flexibility in designing their own suspicious order monitoring systems ("SOMS"). *In re Morris & Dickson Co., LLC*, 88 Fed. Reg. 34523, 34534 (Drug Enf't Admin. May 30, 2023) ("DEA has made clear that it does not endorse any particular system for identifying suspicious orders").

"Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). Additionally, "[a] pharmacy's business model, dispensing patterns, or other characteristics might [render] an order suspicious, despite the particular order not being of unusual size, pattern or frequency." *In re Masters Pharm., Inc.*, 80 Fed. Reg. 55418, 55477 (Drug Enf't Admin. Sept. 15, 2015), *pet. for review denied sub nom. Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017). Distributors are not required to report suspicious orders if they "dispel" the suspicion surrounding those orders. *In re Masters Pharm.*, 80 Fed. Reg. at 55478. To do so, distributors must investigate suspicious orders and dispel all "red flags" indicating "that a customer is engaged in diversion." *Id.* "In general, a red flag is any circumstance that does or should raise a reasonable suspicion as to the validity of a prescription or order." *In re Morris & Dixon Co., LLC*, 88 Fed. Reg. at 34535 n.72 (quotations omitted) (cleaned up).

B

Congress amended the CSA through the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (the "SUPPORT Act"). Effective October 24, 2018, the SUPPORT Act codified the suspicious order reporting requirement. Pub. L. No. 115-271, 132 Stat. 3894 (2018). Since that date the CSA expressly requires distributors to "design and operate a system to identify suspicious orders," and "upon discovering a suspicious order or series of orders, notify the [DEA Administrator] and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business." 21 U.S.C. § 832(a)(1), (3). The statute also incorporates

the regulatory definition of a suspicious order. 21 U.S.C. § 802(57) ("The term 'suspicious order' may include, but is not limited to[] an order of . . . unusual size . . . unusual frequency . . . [or] an order . .. deviating substantially from a normal pattern").

The CSA makes it unlawful to "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 subchapter." 21 U.S.C. § 842(a)(5). Violations of Section 842(a) are punishable by the imposition of civil and criminal penalties, 21 U.S.C. § 842(c)(1)-(2); 28 C.F.R. § 85.5, as well as injunctive relief. 21 U.S.C. § 843(f).

II

Federal Rule of Civil Procedure 12(b)(6) requires plaintiffs to plead factual allegations sufficient to state a claim that is facially "plausible." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim has facial plausibility when the facts pleaded permit a court to make the reasonable inference that the defendant is liable for the alleged misconduct. *Id.*

Determining plausibility is a "context-specific task" requiring a court to use its "judicial experience and common sense." *Schuchardt v. President of the United States*, 839 F.3d 336, 347 (3d Cir. 2016) (quotations omitted). In making this determination, the court assumes well-pleaded facts are true, construes those facts in the light most favorable to the plaintiff, and draws reasonable inferences from them. *Connelly v. Lane Constr. Corp.*, 809 F.3d 780, 790 (3d Cir. 2016).

The Government claims Amerisource violated the suspicious order reporting requirement in four ways. First, it failed to report suspicious orders placed by customers it had notice were potentially diverting controlled substances. (*Id.* ¶¶ 274-431.) Next, it failed to report suspicious orders flagged by its compliance systems and that its compliance staff confirmed were suspicious. (*Id.* ¶¶ 432-42.) Third, it failed to either dispel suspicion relating to orders flagged by its compliance systems or report those orders. (*Id.* ¶¶ 443-85.) Finally, it failed to report suspicious orders that its compliance systems identified, but did not flag, because it deliberately designed those systems to detect fewer such orders. (*Id.* ¶¶ 486-502.)

The Government alleges that Amerisource violated Section 1301.74(b) prior to the SUPPORT Act's effective date and Sections 832(a)(3) and 1301.74(b) after that date. It alleges that noncompliance with both provisions violated Section 842(a)(5). (*Id.* ¶¶ 503-06.) For each of these alleged violations, the Government seeks civil penalties and injunctive relief. (*Id.* ¶ 506.)

III

Amerisource initially contends the term "suspicious order" is unconstitutionally vague and thus violates the Due Process Clause. (Mem. in Supp. of Mot. to Dismiss 31, ECF No. 27.)[3] Amerisource, however, had fair notice that its alleged conduct was prohibited.

[3] The Court uses the page numbers assigned by ECF.

A

Amerisource challenges the CSA's suspicious order reporting requirement on its face as well as applied to its alleged conduct. (Reply in Supp. of Mot. to Dismiss 8, ECF No. 39); (Sept. 19, 2023, Tr. of Oral Arg. 11:13-24, ECF No. 43.) The Government maintains Amerisource can only mount an as-applied challenge. (Mem. in Opp. to Mot. to Dismiss 36-37, ECF No. 38.)

Supreme Court precedent generally prohibits parties from arguing a statute is unconstitutional on its face where they could not successfully maintain an as-applied challenge.[4] *Holder v. Humanitarian Law Project.*, 561 U.S. 1, 18-20 (2010) ("[A] plaintiff who engages in some conduct that is clearly proscribed cannot complain of the vagueness of the law as applied to the conduct of others" (quoting *Vill. of Hoffman Estates v. Flipside*, *Hoffman Estates*, 455 U.S. 489, 495 (1982)); *see also United States v. Mazurie*, 419 U.S. 544, 550 (1975).

The Third Circuit Court of Appeals has applied this principle. *FTC v. Wyndham Worldwide Corp.*, 799 F.3d 236, 256 (3d Cir. 2015) (citing *Mazurie*, 419 U.S. at 550). "[W]hen a litigant's conduct clearly falls within the permissible purview of a statute, such an individual lacks standing to challenge the statute for vagueness, even though the statute may well be vague as applied to others." *Rode v. Dellarciprete*, 845 F.2d 1195, 1200 (3d Cir. 1988) (quotations omitted). In other words, a litigant must show "that the statute under attack is vague as applied to his own conduct, regardless of its potentially vague application to others." *Aiello v. Wilmington*, 623 F.2d 845, 850 (3d

[4] Exceptions to this general rule are not relevant here. *See, e.g.*, *United States v. Requena*, 980 F.3d 29, 40 (2d Cir. 2020) ("we have often declined to entertain facial challenges where the challenger asserts no infringement of First Amendment or other fundamental rights protected by the Constitution").

Cir. 1980); *NAACP v. City of Philadelphia*, 39 F. Supp. 3d 611, 616 (E.D. Pa. 2014) (quoting *Aiello*, 623 F.2d at 850). Inquiries into whether a statute is void for vagueness are "completed on a case-by-case basis, and the party opposing the statute or standard must show that it is vague as applied to him." *Borden v. Sch. Dist.*, 523 F.3d 153, 166-67 (3d Cir. 2008).

A few courts have more recently questioned whether the Supreme Court's decision in *Johnson v. United States*, 576 U.S. 591 (2015) changes this analysis. *Johnson* rejected the rule that "a statute is void for vagueness only if it is vague in all applications," *id.* at 602-03, which some courts have understood to be the basis for limiting facial vagueness challenges to situations where the law is also vague as applied to the challenger's conduct. *See, e.g.*, *United States Telecom Ass'n v. FCC*, 825 F.3d 674, 735-36 (D.C. Cir. 2016) (noting the tension between *Johnson* and *Holder*); *United States v. McHugh*, 583 F. Supp. 3d 1, 24 n.20 (D.C. Cir. 2015) (same); *United States v. Morales-Lopez*, No. 2:20-cr-00027, 2022 WL 2355920, 2022 U.S. Dist. LEXIS 117038, at *10-18 (D. Utah June 30, 2022) (same).

Most courts, however, have disagreed. *See United States v. Hasson*, 26 F.4th 610, 620 (4th Cir. 2022) ("the *Johnson* Court did not silently overrule its precedents prohibiting vagueness challenges by those whose conduct a statute clearly prohibits"), *cert. denied* 143 S. Ct. 310 (2022); *Bowling v. McDonough*, 38 F.4th 1051, 1061 (Fed. Cir. 2022) ("a person to whom a law is not vague *as applied* to that person's situation cannot assert facial vagueness . . . this principle survives *Johnson*") (emphasis in original); *see also United States v. Cook*, 970 F.3d 866, 877 (7th Cir. 2020); *United States v. Bramer*, 832 F.3d 908, 909-10 (8th Cir. 2016); *303 Creative LLC v. Elenis*, 6

F.4th 1160, 1189-90 (10th Cir. 2021), *rev'd on other grounds*, 600 U.S. 570 (2023); *Kashem v. Barr*, 941 F.3d 358, 376-77 (9th Cir. 2019). Notably, the Third Circuit appeared to follow this rule two months after *Johnson* was decided. *See Wyndham*, 799 F.3d at 256. It applied it again three years ago. *United States v. Portanova*, 961 F.3d 252, 263 (3d Cir. 2020) ("Because vagueness challenges are evaluated on a case by case basis, we must examine the statute to determine if it is vague as applied to Portanova") (cleaned up). The Court accordingly assesses Amerisource's void-for-vagueness challenge as applied to its own alleged conduct.

B

1

Because courts assume "man is free to steer between lawful and unlawful conduct," due process requires laws to clearly define the conduct they prohibit. *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). A statute or regulation is unconstitutionally vague if it "fails to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement." *United States v. Williams*, 553 U.S. 285, 304 (2008).[5]

[5] The Government contends the Court should apply a lower standard when assessing whether the suspicious order reporting requirement is vague. (Mem. in Opp. to Mot. to Dismiss 34-36.) In the Third Circuit, courts will only find an "economic civil statute" unconstitutionally vague if it is "so vague as to be no rule or standard at all." *CMR D.N. Corp. & Marina Towers Ltd. v. City of Philadelphia*, 703 F.3d 612, 632 (3d Cir. 2013) (quotations omitted); *Wyndham*, 799 F.3d at 250. Some civil statutes, however, are subject to the more searching review afforded to criminal statutes. *Wyndham*, 799 F.3d at 255 n.20. The higher standard applies when civil statutes contain "quasi-criminal penalties." *Id.*; *Advance Pharm., Inc. v. United States*, 391 F.3d 377, 396 (2d Cir. 2004); *United States v. Clinical Leasing Serv., Inc.*, 925 F.2d 120, 122 & n.2 (5th Cir. 1991).

Because the suspicious order reporting requirements survive a vagueness challenge under the criminal standard, the Court need not decide whether Section 842(a)(5) imposes quasi-criminal penalties. *See San Filippo v. Bongiovanni*, 961 F.2d 1125, 1139 (3d Cir. 1992) ("Certainly if such general standards in criminal statutes are sufficiently precise to withstand attack as void for

In the criminal context, vagueness challenges based on a lack of fair notice "may be overcome in any specific case where reasonable persons would know their conduct puts them at risk of punishment under the statute." *United States v. Ferriero*, 866 F.3d 107, 124 (3d Cir. 2017) (quotations omitted). A criminal statute therefore "need only give fair warning that certain conduct is prohibited." *Id.* (quotations omitted). A criminal statute is not unconstitutionally vague simply because it "could have been written more precisely." *United States v. Fullmer*, 584 F.3d 132, 152 (3d Cir. 2009) (quotations omitted). Flexible standards do not make a statute or regulation impermissibly vague, *Ward v. Rock Against Racism*, 491 U.S. 781, 794 (1989), and due process does not prohibit implementing officials from exercising "considerable discretion," *id.*

Moreover, where "a statute or regulation is aimed at a class of people with specialized knowledge of what is being regulated, then the specificity required by due process is measured by the common understanding of that group." *United States v. Ward*, No. 00-681, 2001 WL 1160168, 2001 U.S. Dist LEXIS 15897, at *13-14 (E.D. Pa. Sept. 5, 2001); *see also Precious Metals Assocs., Inc. v. CFTC*, 620 F.2d 900, 907 (1st Cir. 1980).

2

Amerisource cannot credibly claim that it lacked fair notice that the orders at issue in this case qualified as suspicious. The Government accuses Amerisource of failing to report orders designated as suspicious by human reviewers, orders flagged by its systems but not cleared of suspicion, and orders from pharmacies that it had notice

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vagueness, analogous standards in the civil context where less specificity is required satisfy due process").

were likely facilitating diversion. While Amerisource argues that "the term 'suspicious orders' is hopelessly vague and subjective," (Mem. in Supp. of Mot. to Dismiss 9), the Government does not seek to impose novel interpretations of the CSA by ambush. It relies on established applications of the law.

i

Amerisource was on notice that orders allegedly satisfying its SOMS's thresholds qualified as suspicious. The D.C. Circuit Court of Appeals' decision in *Masters Pharm., Inc. v. DEA* teaches that orders flagged by a distributor's SOMS are suspicious if, under that SOMS, "[a]s a matter of common sense and ordinary language," they display unusual size or unusual frequency or deviate substantially from a normal pattern. 861 F.3d 206, 216-17 (D.C. Cir. 2017). The fact that this inquiry is therefore context specific does not make it "so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application." *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926). And as explained in subsection IV.B.2.ii, *infra*, orders allegedly flagged by Amerisource's SOMS were suspicious because they displayed unusual size and deviated substantially from normal patterns. 21 U.S.C. § 802(57); 21 C.F.R. § 1301.74(b).

Moreover, the Government alleges Amerisource's own misconduct shows it knew its reporting requirements. Amerisource, for instance, cleared flagged orders on grounds that were "manifestly false," or based on "implausible conclusions." (Compl. ¶¶ 449-72.) The Government further asserts Amerisource intentionally established "exceedingly narrow parameters for flagging suspicious orders," in order to limit its reporting obligations and "applauded its success" in doing so. (*Id.* ¶¶ 196-206.) Amerisource cannot allegedly work to circumvent or minimize its reporting obligations

and simultaneously claim not to understand them. "[O]ne who deliberately goes perilously close to an area of proscribed conduct shall take the risk that he may cross the line." *United States v. Hoffert*, 949 F.3d 782, 788 (3d Cir. 2020) (quoting *Boyce Motor Lines, Inc. v. United States*, 342 U.S. 337, 340 (1952)).

Specifically, the Government accuses Amerisource of manually adjusting customers' algorithmic flagging thresholds to circumvent its obligation to report or investigate orders from those customers. (Compl. ¶¶ 161-62. 494, 498, 501.) And the Government alleges that Amerisource told the DEA that "rejected orders are also reported to the DEA as suspicious," when it in fact allegedly instructed its reviewers not to report rejected orders unless they determined that the substances ordered were "more likely than not being diverted." (*Id.* ¶¶ 435-36.) The Government further asserts that Amerisource celebrated its success in designing a system to flag fewer orders. (*Id.* ¶¶ 204-06.)

ii

Amerisource was also on notice that its customers' alleged diversion of controlled substances rendered orders suspicious. Amerisource cannot claim it didn't know that this alleged fact independently triggered its reporting obligations, even if orders from these customers did not display unusual size or frequency or deviate substantially from normal patterns. Unusual size, unusual frequency, and substantial deviation from a normal pattern are "illustrative examples[] rather than an exclusive list of indicia" of suspicion. *Masters*, 861 F.3d at 221 (internal quotation marks omitted). A customer pharmacy's "business model, dispensing patterns, or other characteristics might make

an order suspicious, despite the particular order not being of unusual size, pattern or frequency." *In re Masters Pharm*, 80 Fed. Reg. at 55477 (quotations omitted). The DEA Administrator has already addressed and rejected a claim that this reading "violates due process by failing to provide fair warning of what constitutes a suspicious order, or when a report is required of a registrant." *Id.* at 55473 (quotations omitted).

Customers' business practices have long been recognized as indicia of suspicious orders. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36487, 36497, 36501-02 (Drug Enf't Admin. July 3, 2007); *Masters*, 861 F.3d at 221 ("DEA reasonably concluded that other indicia may also raise suspicions about an order for controlled substances. That conclusion was entirely consistent with the text of the regulation, as well as agency precedent") (citing *Southwood*, 72 Fed. Reg. at 36497, 36501-02). These "[p]ast adjudications . . . give added precision" to the suspicious order reporting requirement. *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 395 (1969); *see also Dirks v. SEC*, 802 F.2d 1468, 1471 (D.C. Cir. 1986) ("turning a blind eye to administrative glosses on the statute brushes past the core concern of [the] vagueness doctrine, namely that an individual be provided with sufficient warning that certain conduct is proscribed").

The Government claims Amerisource filled orders for pharmacies even though it had notice that drug deals were occurring in their parking lots, that these pharmacies were filling prescriptions that no other pharmacies would fill, and that they were selling large percentages of their prescriptions for cash. (Compl. ¶¶ 367-431.) The Government also alleges Amerisource continued to fill orders from these customers without reporting or further investigating them, even though it threatened to stop selling to them. (*Id.* ¶¶ 376-83, 390-98, 413-28.)

iii

Nor is the CSA standardless enough to invite arbitrary enforcement. Amerisource argues it does not know whether an order of unusual size includes orders four times the size of an ordering pharmacy's average, three times the size, or both, and that "[t]his lack of clarity can lead to arbitrary enforcement." (Mem. in Supp. of Mot. to Dismiss 32.) But whether an order is suspicious does not depend on "statistical certainty." *In re Masters Pharm.*, 80 Fed. Reg. at 55480. Evidence need only "create a suspicion, a standard which is less than that of probable cause," that a customer is diverting controlled substances. *Id.* If a given distributor's SOMS flags orders because they, under that SOMS's algorithmic criteria, display unusual size or frequency or deviate substantially from a normal pattern, the distributor must report those orders or dispel suspicion. The same obligation applies when customers' business practices indicate potential diversion.

Amerisource offers a hypothetical example where one distributor faces liability for failing to report an order 3.5 times larger than average because their SOMS flagged such orders while another distributor's SOMS did not. (Mem. in Supp. of Mot. to Dismiss 33.) But this example does not demonstrate arbitrary enforcement; it shows that only one distributor "discovered" the order at all and was required to report it in the first place. 21 C.F.R. § 1301.74(b) (suspicious orders must be reported when discovered); 21 U.S.C. §832(a)(3) (same). The example illustrates the application of a qualitative standard to distributors using different flagging criteria.

The reporting requirement imposes qualitative standards rather than drawing precise and discrete lines in the sand. The fact that *Masters* "common sense and

ordinary language" inquiry must be applied to distinct SOMS that operate in different ways does not render it "standardless." *See Williams*, 553 U.S. at 304 (a provision is vague if it is "so standardless that it authorizes or encourages seriously discriminatory enforcement"). And the Supreme Court has explained that it does not "doubt the constitutionality of laws that call for the application of a qualitative standard such as 'substantial risk' to real-world conduct; 'the law is full of instances where a man's fate depends on his estimating rightly . . . some matter of degree.'" *Johnson v. United States*, 576 U.S. 591, 603-04 (2015) (quoting *Nash v. United States*, 229 U.S. 373, 377 (1913)).

IV

Amerisource next contends that it cannot be liable for failing to report those orders the Government believes were suspicious because it was never required to report them in the first place. Specifically, Amerisource claims, because its systems do not treat orders as suspicious until they are affirmatively designated as such by human reviewers, there was "no suspicion to 'dispel' with respect to the orders of interest flagged by the computer algorithm." (Mem. in Supp. of Mot. To Dismiss 41.) But Amerisource cannot unilaterally modify its reporting obligations; neither Section 1301.74(b) nor the CSA empower distributors to rewrite the law.

In *Masters*, the D.C. Circuit Court of Appeals denied a controlled substance distributor's petition for review of a DEA decision revoking its certificate of registration for violating Section 1301.74(b). 861 F.3d at 212. Masters' SOMS consisted of a computer program and a protocol for human review. Once the computer program held orders for human review, Masters' staff took specified investigative steps, after which

they could either deem the order suspicious or "non-suspicious." *Id.* at 213-14. Suspicious orders were to be reported to DEA. *Id.* at 214. The Court of Appeals denied the petition because the DEA Administrator had reasonably concluded that these orders were suspicious under the regulatory definition. *Id.* at 216-17.

Amerisource asserts that the Government cannot judge its conduct against *Masters*' analytical framework because the operating systems it maintained during the relevant period are distinct from the operating system at issue in that case. (Mem. in Supp. of Mot. to Dismiss 40-41.) This misreads *Masters*. Whether an order is suspicious does not depend on what a given distributor says or how its system is structured. The definition of a suspicious order is fixed by the CSA, just as it was by Section 1301.74(b) prior to the passage of the SUPPORT Act.

Whether a distributor has notice of suspicious orders is specific to that distributor's screening criteria. But whether orders that a distributor *does* have notice of qualify as "suspicious" is a separate question, and one that does not depend on the screening criteria employed. The CSA provides a fixed definition, one which the entities it regulates cannot unilaterally circumvent or supplant. When they receive suspicious orders, distributors must either dispel suspicion or report these orders to DEA. And the Government has plausibly alleged Amerisource failed to do so.

A

1

In his revocation decision, the DEA Administrator reviewed Masters' operating system manual and concluded that any order the company's computer program held "was held due to its unusual size, frequency, or pattern," the criteria that Section

1301.74(b) "expressly provide" as "indicia that give rise to a suspicion." *Id.* at 215. Masters was therefore obligated to report orders held by the computer program to DEA unless Masters dispelled suspicion. *Id.*

Masters challenged this determination. Pointing to its compliance manual, Masters argued that the program flagged "all orders that have even the *potential* to be suspicious," in addition to suspicious orders as defined by Section 1301.74(b). *Id.* at 216 (emphasis added). Masters asserted that its systems deemed an order suspicious only if it was "held by the Computer Program *and* a Masters employee follow[ed] up and separately [made] a determination that it [was] suspicious." *Id.* (emphasis in original).

The Court of Appeals first noted that Masters' reading of its own compliance manual was "strained," explaining that the manual said the computer program was "designed to hold orders that are suspicious within the meaning of" Section 1301.74(b). *Id.* The court did not, however, rest its conclusion on how Masters' program defined suspicious orders, finding that Masters' own definition of suspicious orders was not the proper inquiry. "More fundamentally," the court explained, "the key question in this case is not whether held orders qualified as 'suspicious' under Masters' policies; the question is whether they qualified as 'suspicious' under [Section] 1301.74(b)." *Id.* In other words, the "relevant inquiry" did not turn on what Masters said suspicious meant, it turned on "how far the language of the regulation reaches." *Id.*

Specifically, Masters' program held orders if: (1) combined with other orders in the same thirty-day window, they requested more doses of a controlled medication than the ordering pharmacy had requested in any of the preceding six months; (2) the pharmacy ordered a controlled medication more frequently in thirty days than it had in

any of the preceding six months; or (3) the pharmacy's ordering pattern for a controlled medication deviated "in some other notable way from its ordering pattern" over the prior six months. *Id.* The court reasoned that "as a matter of common sense and ordinary language," orders deviating from a six-month trend were "unusual" rather than "normal." *Id.* It was therefore "entirely reasonable for the Administrator to hold that orders held by the Computer Program met the *regulatory definition* of suspicious orders unless Masters' staff dispelled the suspicion." *Id.* at 216-17 (internal quotation marks omitted) (emphasis added).

2

Consistent with *Masters*, when its algorithms flagged orders, Amerisource "discovered" those orders, triggering its reporting obligation. 21 U.S.C. § 832(a)(3); 21 C.F.R. § 1301.74(b). Upon discovering these orders, Amerisource could decline to report them only if it dispelled suspicion. *Masters*, 861 F.3d at 222. Specifically, while "a distributor's investigation of the order . . . may properly lead it to conclude that the order is not suspicious, the investigation must dispel all red flags [indicating] that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor 'inform' the Agency about the order." *In re Masters Pharm.*, 80 Fed. Reg. at 55478.

Amerisource is incorrect that *Masters* "is of no import here," (Sept. 19, Tr. of Oral Arg. 25:4), even though *Masters* did not mandate that other distributors use the same SOMS as the one at issue in that case. (Mem. in Supp. of Mot. To Dismiss 40-41.); *City of Huntington v. AmerisourceBergen Drug Corp.*, 609 F. Supp. 3d 408, 442 (S.D. W.Va.

2022) ("In *Masters*, the distributor's conduct was judged against the failures evident when applying its own SOM program").

Masters is distributor and SOMS-specific with respect to whether a distributor has discovered a suspicious order and whether that order is, compared to other orders a distributor receives, unusual in size, frequency, or pattern. *Masters*, 861 F.3d at 216-17, 221-22. The need to tailor an analysis to a specific distributor's SOMS logically follows from the fact that liability depends on whether that distributor "discovered" suspicious orders. 21 U.S.C. § 832(a)(3) (requiring reporting "upon discovering a suspicious order or series of orders"); 21 C.F.R. 1301.74(b) (requiring reporting of suspicious orders "when discovered"). Determining whether orders are suspicious is a comparative, case-by-case exercise, but this does not mean distributors can redefine "suspicious" as they see fit.

While different SOMS may vary, so long as a distributor's SOMS flags orders that satisfy the statutory definition of "suspicious," those orders must be reported unless the distributor dispels their suspicion. *Masters*, 861 F.3d at 216-18, 220-22. While orders flagged by one distributor's SOMS may not be flagged by another distributor's, the definition of "suspicious" remains the same in either case. *Id.* at 216. If a given SOMS captures orders satisfying this definition, that order has been discovered and triggers the distributor's reporting obligations unless that distributor dispels the suspicion. *Id.* at 216-18

Though it did not mandate that other distributors use a given SOMS, *Masters* explained "what *a distributor in Masters' position* must do if, instead of reporting to DEA all orders of unusual size, frequency, or pattern, it chooses to use the SOMS—or

an equivalent program—to seek to dispel the suspicion." *Id.* at 222 (emphasis added). It need not investigate orders at all if it reports them to the DEA. *Id.* But if it "chooses to shoulder the burden of dispelling suspicion," and "uses something like [algorithmic flagging combined with human review] to guide its efforts, then the distributor must actually undertake the investigation" and report orders "that still appear suspicious after investigation." *Id.*

Therefore, when a system is crafted to capture orders that satisfy the statutory definition of suspicious, a distributor cannot make the order's status contingent on an affirmative designation by a human reviewer. "[U]pon [a distributor's] receipt of an order meeting one of the criteria set forth in [Section] 1301.74(b), the order must either be reported as suspicious or investigated . . . the investigation must dispel the suspicion in order to excuse a distributor from its obligation to report the order." *In re Masters Pharm.*, 80 Fed. Reg. at 55479 n.164.[6] Distributors enjoy flexibility in designing their systems, but not in deciding if orders those systems catch qualify as suspicious.

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[6] The DEA may establish a statute's contours "through a series of adjudications" and "[rely] on its precedent." *PDK Labs, Inc. v. U.S. Drug Enf't Admin.*, 438 F.3d 1184, 1195 (D.C. Cir. 2004). The nature of agency adjudication is that "similarly situated non-parties may be affected by the policy or precedent applied, or even merely announced in dicta." *Goodman v. FCC*, 182 F.3d 987, 994 (D.C. Cir. 1999). And while *Masters* and the administrative decisions it cites interpreted Section 1301.74(b) before it was codified into the CSA, Sections 802 and 832's nearly identical language do not indicate any congressional intent to modify its meaning. *See Davis v. Mich. Dep't of the Treasury*, 489 U.S. 803, 813 (1989) ("When Congress codifies a judicially defined concept, it is presumed, absent an express statement to the contrary, that Congress intended to adopt the interpretation placed on that concept by the courts").

Consequently, in cases involving similar allegations, courts have relied on DEA registration revocation orders to determine "the extent of [distributors'] duties under the CSA and its regulations." *See, e.g.*, *In re Nat'l Opiate Prescription Opiate Litig.*, No. 1:17-md-2804, 2019 WL 3917575, 2019 U.S. Dist. LEXIS 140020 at *74-75 (N.D. Ohio Aug. 19, 2019) ("The DEA's adjudicative decisions in *Southwood* and *Masters* [] provide further support for the Court's conclusion"); *Cervase v. Off. of the Fed. Reg.*, 580 F.2d 1166, 1168 (3d Cir. 1978) ("Publication of [a] document in the Federal Register makes it effective against the world" and is "sufficient to give notice to any person subject to or affected by the document").

Finding otherwise would allow distributors to subject themselves to their own strategically crafted standards, something anathema to the CSA's central purpose. Such a result would enable distributors to treat suspicious orders flagged by their systems as non-suspicious, notwithstanding the statutory definition. This outcome would turn agency precedent on its head. When a distributor's system "places a hold on a customer's order for controlled substances because the order is of unusual size, pattern, or frequency, the order meets the specific criteria of being suspicious." *In re Morris & Dickson Co., LLC*, 88 Fed. Reg. at 34534 (citing *In re Masters Pharm.*, 80 Fed. Reg. at 55479 and *Masters*, 861 F.3d at 216-17).

Amerisource's interpretation would also undermine the purpose behind giving distributors flexibility in designing their own systems. At oral argument, Amerisource explained "there are millions of reasons why orders get processed that might pop up depending on your algorithms in your system." (Sept. 19, Tr. of Oral Arg. 32:11-13). A system's flagging criteria determines which orders it catches. But this flexibility illustrates the importance of maintaining a uniform trigger for the reporting obligation. If distributors can manipulate their systems to define the meaning of a suspicious order, the reporting requirement would be meaningless. *See Masters*, 861 F.3d at 221.

Amerisource believes that allowing it to treat flagged orders as non-suspicious even if they satisfy the statutory definition "does not provide [distributors] with free rein," since DEA can suspend, revoke or disapprove a distributor's registration or make adverse audit findings if a distributor fails to maintain a "satisfactory system." (Mem. in Supp. of Mot. To Dismiss 38.) But these administrative enforcement remedies are

"independent of, and not in lieu of, criminal prosecutions or other proceedings under this title or any other law of the United States." 21 U.S.C. § 824(c)(4).

Moreover, Amerisource ignores that its interpretation would also restrict the evidence DEA uses in revocation proceedings. The DEA can, and does, rely on distributors' failure to report suspicious orders as a basis for revocation, as the *Masters* decision illustrates. *Masters*, 861 F.3d at 212 ("The revocation order turned on DEA's conclusion that Masters had shirked its legal obligation to report suspicious orders for controlled substances"). While reporting failures are not the only basis for registration revocations, *see* 21 U.S.C. § 824(a), allowing each distributor to redefine suspicious orders would impact the agency's ability to exercise its supervisory role.

Finally, while the DEA can institute revocation proceedings independent of any actions seeking civil penalties, Amerisource's proposed interpretation would impede the CSA's incentive structure. If a distributor designed a system that detected suspicious orders but deliberately did not designate them as such, DEA could, and likely would, seek revocation of its registration for failing to maintain "effective controls against diversion." 21 U.S.C. § 823(a)(1); 21 C.F.R. § 1301.74(b). But under Amerisource's approach, all accompanying violations of the reporting requirement could not also serve as a basis for civil penalties. Such a result would incorporate the "one free bite" rule into the CSA's civil penalty provisions, contrary to the statute's plain text. *See* 21 U.S.C. § 842(c)(1) (detailing the availability of civil penalties).

Moreover, revocation is a severe penalty. The alternative of civil penalties enables DEA to enforce the reporting requirement without needing to remove distributors from the market, and to respond to smaller-scale violations in a

proportionate manner. Amerisource has expressed legitimate concerns regarding "patient access to needed medications" (Mem. in Supp. of Mot. to Dismiss 45), but its own proffered interpretation of the reporting requirement would force DEA to choose between further restricting patient access or letting distributors off the hook.[7]

At bottom, Congress imposed upon distributors a legal obligation to report suspicious orders, 21 U.S.C. § 842(a)(3), a duty that previously existed pursuant to federal regulation. 21 C.F.R. § 1301.74(b). Congress would not codify a legal obligation and simultaneously authorize its circumvention.

B

Again, the Government accuses Amerisource of violating the CSA in four ways. (Mem. in Opp. to Mot. To Dismiss 22.) Because the Government's second, third and fourth categories of alleged violations require more direct application of the Court's interpretation of *Masters,* the Court addresses them first.

1

The second category of Amerisource's alleged CSA violations pertains to those orders Amerisource designated as suspicious; the Government alleges Amerisource failed to report orders that its systems flagged and that it affirmatively confirmed were

[7] Amerisource also argues that the reporting requirement threatens patient access because distributors will not be able to ship any suspicious order they report until they dispel the suspicion of those orders. (Mem. in Supp. of Mot. to Dismiss 45.) First articulated in *Southwood*, the "shipping requirement" mandates distributors exercise "due diligence before shipping any suspicious order." *Masters*, 861 F.3d at 221-22.

But the shipping requirement does not apply to all suspicious orders because distributors can ship suspicious orders that they report as long as they are "able to determine [those orders are] not *likely* to be diverted into illegal channels." *Id.* at 212-13 (emphasis added). And the amount of evidence needed to show suspicion is much lower than the amount needed to show that something is likely. *Id.* at 215 (quotations omitted); *see also In re Masters Pharm.*, 80 Fed. Reg. at 55478 (rejecting the conclusion that diversion must be "likely" for orders to be suspicious because this approach "conflates the standard for whether an order can be shipped . . . with that for whether the order must be reported as suspicious").

suspicious. (Compl. ¶ 432.); (Memo. in Opp. to Mot. to Dismiss 27.) Amerisource allegedly concluded that it could not fill these orders because its reviewers could not dispel suspicion surrounding them, but even then, Amerisource did not report the orders to the DEA. (*Id.* ¶¶ 432, 438.) Amerisource's written guidance allegedly directed its human reviewers to "reject all flagged orders for which they could not dispel suspicion, but to report a rejected suspicious order only if the reviewer determined that the ordered controlled substance was *more likely than not* being diverted." (Compl. ¶ 436) (emphasis added). Amerisource's alleged practice of rejecting suspicious orders but not reporting them unless the substances were "more likely than not being diverted" vitiates the meaning of "suspicious."

In *In re Masters Pharm.*, the DEA Administrator rejected the ALJ's conclusion that it must be "likely that controlled substances will be diverted to trigger the reporting requirement." 80 Fed. Reg. at 55420 (internal quotation marks omitted). Such a standard is higher than that of "the plain language of the regulation."[8] *Id.* Both Section 1301.74(b) and Section 832(a)(3) of the CSA "require[] only that the order be suspicious, a standard which is less than that of probable cause." *Id.* The Court of Appeals also recognized this difference between standards when it denied Masters' petition to review the Administrator's decision. *Masters*, 861 F.3d at 214-15.

The Government alleges "even after [Amerisource] stopped providing this guidance in writing," it continued reporting only those rejected orders that reviewers determined were "more likely than not being diverted." (Compl. ¶¶ 436-37.) For instance, Amerisource allegedly rejected an order but did not report it even though a

[8] The DEA Administrator's and subsequent Court of Appeals decision refer only to Section 1301.74(b)'s reporting requirement because they occurred in 2015 and 2017, prior to the SUPPORT Act's enactment.

CSRA reviewer wrote "investigate . . . [o]rder [q]uantity [e]xceeds threshold; not to release." (*Id.* ¶441.) The Complaint alleges the same behavior with respect to an order that a reviewer noted was "for a high risk family," bore a "high risk" of over consumption, and was "not compliant." (*Id.* ¶ 440.) And as the Government notes, Amerisource does not dispute that it "concluded the orders were suspicious but still failed to report" them. (Mem. in Opp. to Mot. to Dismiss 27.) These assertions plausibly allege violations of Amerisource's reporting obligations. 21 U.S.C. § 842(a)(5); U.S.C. § 832(a); 21 C.F.R. § 1301.74(b).

2

i

The third category of Amerisource's alleged CSA violations concern orders that Amerisource's systems flagged but were never affirmatively designated as suspicious by its human reviewers.

Again, *Masters* explains that distributors can control only whether their systems capture orders that meet the statutory definition of suspicious. they cannot redefine the meaning of "suspicious order." *Masters*, 861 F.3d at 216-17. Amerisource nonetheless insists that the orders flagged by its systems were not suspicious because human reviewers never affirmatively designated them as such. (Mem. in Supp. of Mot. to Dismiss 39-41.) Amerisource argues that orders that were only flagged by its systems had "no suspicion to dispel." (*Id.* at 41) (internal quotation marks omitted). But again, Amerisource cannot use its own system's technicalities to redefine the CSA and regulations.

Consequently, whether Amerisource labeled the orders it flagged as suspicious or not is irrelevant. When a distributor receives an order "meeting one of the criteria set forth in [Section] 1301.74(b), the order must either be reported as suspicious or investigated." *In re Masters Pharm.*, 80 Fed. Reg. at 55479 n.164. And when a distributor chooses to investigate the order, "the investigation must *dispel* the suspicion in order to excuse a distributor from its obligation to report the order." *Id.* If the orders Amerisource's SOMS flagged were of an unusual size or frequency or deviated substantially from a normal pattern, they were suspicious.

ii

The Government alleges that Amerisource's first computer-based Order Monitoring Program, or OMP, worked by dividing controlled substances into different groups called "drug families," and dividing customers into "customer peer groups," of extra-large, large, medium and small, based on their dollar volumes. (Compl. ¶¶ 149-55.) OMP allegedly set thresholds for each of these groups. (*Id.* ¶ 156.) These thresholds established the maximum amount of drugs in a given drug family that a customer could order in a 30-day window. (*Id.*) Amerisource allegedly set a customer's threshold at "roughly three times the customer's peer group's average total orders for a 30-day period;" orders exceeding these thresholds were flagged for human review. (*Id.* ¶¶ 157-58.)

Consequently, the Government alleges, OMP typically did not flag orders for review unless a customer's ordering in a 30-day period exceeded its peers' average orders by 300%. (*Id.* ¶ 160.) The Government further alleges that Amerisource could raise customers' thresholds on request, and when it did so, automatically shipped

orders that "dramatically exceeded" this default threshold without holding them for review. (*Id.* ¶ 161.) The Government alleges that OMP flagged under 1% of orders placed with Amerisource. (*Id.* ¶ 162.)

Amerisource's SOMS are not the same as Masters'. But their alleged flagging criteria demonstrate that the orders they held for human review qualified as suspicious. OMP allegedly set a heightened threshold by only flagging orders that were three-times as large as comparably sized customers' 30-day averages. "As a matter of common sense and ordinary language," *Masters*, 861 F.3d at 216, orders allegedly meeting these criteria reasonably qualify as orders of unusual size and therefore satisfy the statutory definition of suspicious.

The same goes for orders allegedly flagged by Amerisource's Revised Order Monitoring Program, or ROMP. The Government alleges that Amerisource developed ROMP to deliberately flag fewer orders, reducing its reporting obligations. (Compl. ¶ 170.) ROMP allegedly relied on a "dual-trigger requirement," under which orders would be flagged only if they triggered at least two of three possible thresholds. (*Id.* ¶¶ 184-85.)

The first threshold compared a customer's orders against its own ordering history for a particular drug family to determine whether they were unusual in size. (*Id.* ¶ 181.) ROMP did so by using algorithms to determine whether a customer's order was unusual compared to its historical purchasing for the same drug family. (*Id.*) The second threshold resembled the original OMP threshold; it allegedly determined whether orders were unusual by comparing the customer's prior 30 days of orders for the ordered drug family to a customer peer group's average purchases of the same drug

family. (*Id.* ¶ 182.) This threshold was designed to flag 30-day ordering patterns that were outliers in comparison to peer customers' ordering patterns. (*Id.*) The third threshold was normally calculated by multiplying the second threshold by a factor of up to 10. (*Id.* ¶ 183.) The Government alleges that the second threshold identified substantially unusual ordering patterns and the third identified "extremely abnormal ordering patterns." (*Id.* ¶ 182-83.) This system, then, allegedly flagged for human review only orders of both unusual size or pattern or orders of extremely abnormal ordering patterns. (*Id.* ¶ 185.) The Government also alleges that Amerisource, through CSRA, retained its ability to increase a given customer's thresholds "upon request." (*Id.* ¶ 195.)

The Government has plausibly alleged that Amerisource breached its duty to report suspicious orders when it failed to report orders held by its dual-trigger ROMP system. Orders flagged for deviating from a customer's historical purchases of drugs in the same "family" qualify as "unusual" rather than "normal." (*Id.* ¶¶ 212-14); *Masters*, 861 F.3d at 216-17. Similarly, orders that are outliers in comparison to a peer group's orders of a drug family in a 30-day period deviate substantially from a normal pattern. Necessarily then, orders exceeding this second threshold by a factor of up to 10 also qualify as substantial deviations from the norm.[9]

Under the facts alleged, each of the ROMP thresholds reasonably satisfy the statutory definition of suspicious. An order meets this definition if it displays unusual

[9] This conclusion is buttressed by some of the Government's alleged examples. ROMP allegedly flagged one order that exceeded the first threshold by 260% and the second by over 1,000%. (Compl. ¶ 467.) Another allegedly exceeded the second threshold by over 500%. (*Id.* ¶ 490.) A third allegedly exceeded the second threshold even after Amerisource manually increased the customer's threshold over the peer-based default level "by a factor of more than 14." (*Id.* ¶ 498.) Orders allegedly flagged for triggering not one, but two of these three thresholds satisfied the statutory definition of "suspicious order."

size *or* unusual frequency *or* deviates substantially from a normal pattern. Upon receiving "an order *meeting one of the criteria* set forth in [Section] 1301.74(b), the order must either be reported as suspicious or investigated" (emphasis added). *In re Masters Pharm.*, 80 Fed. Reg. at 55479. The reporting obligation depends on whether a distributor discovers orders meeting the statutory definition, not on whether it discovers multiple, independently sufficient indicia of suspicion. The same goes for orders ROMP actually flagged, since these orders triggered two of these thresholds.

The Government also alleges that the orders flagged by ICS's electronic order monitoring program were suspicious. This system too allegedly held unusual orders that breached statistical thresholds. (Compl. ¶¶ 254-57.) The Government contends this program affirmatively designated held orders as suspicious and that ICS's policies directed reviewers to investigate these orders and report them to DEA if they did not dispel suspicion. (*Id.* ¶¶ 259, 265.) But the Government alleges that Amerisource "routinely" cleared held orders without investigating them. (*Id.* ¶ 261.) And these orders satisfy the statutory definition because they were flagged if they exceeded statistical thresholds, rendering them unusual. (Compl. ¶¶ 254-57.)

Additionally, ICS's policies also "categorically provided that controlled-substance orders placed by customers who were themselves distributors were not suspicious." (*Id.* ¶ 262.) Therefore, the Government has also plausibly alleged that Amerisource failed to report orders flagged by this system that human reviewers did not affirmatively designate as suspicious. (*Id.* ¶¶ 268-70.)

iii

The Government has alleged sufficient facts to show that Amerisource failed to report flagged orders without first dispelling suspicion. It contends Amerisource's order reviewers "cleared and did not report an extremely high percentage of flagged orders," asserting that, for example, over 99% of "highly unusual, flagged orders" were not reported in 2017. (*Id.* ¶¶ 249-50.) For instance, reviewers allegedly cleared and did not report flagged orders after "cursory reviews of a few seconds or minutes, without actually dispelling the suspicion flagged." (*Id.* ¶ 445.) Additionally, reviewers allegedly cleared orders for fentanyl products on the false ground that they were "not subject to diversion or abuse." (*Id.* ¶¶ 449-58.) In another instance, an order for promethazine and codeine syrup—the same one allegedly flagged for exceeding ROMP's first and second thresholds by over 260% and 1,000%, respectively—was approved as "within acceptable range." (*Id.* ¶¶ 466-69.) Some flagged orders were allegedly "approved for release" or "[a]pproved as compliant," with no additional information given. (*Id.* ¶¶ 473-75.) This limited documentation, the Government asserts, shows that Amerisource's investigations were inadequate. (*Id.* ¶¶ 446-47.)[10]

[10] Amerisource's own policies allegedly required its order reviewers to "document their review of each flagged order and justify their decisions whether to ship or reject the order and whether to report the order." (*Id.* ¶ 215.) The Government therefore argues that the alleged absence of such documentation is "compelling evidence" that Amerisource violated the CSA by failing to dispel the suspicion of these orders. (Mem. in Opp. to Mot. to Dismiss 30); *see also Masters*, 861 F.3d at 217-18 (explaining that the absence of documentation required by a distributor's system constitutes evidence that the distributor did not take investigative steps); Fed. R. Evid. 803(7) (a matter's absence from a record of a regularly conducted activity can be used to show that "the matter did not occur or exist"). The Government does not allege Amerisource was required to document these investigations or that failing to do so subjects it to any penalties. (Sept. 19, Tr. of Oral Arg. 83:8-84:2); (Mem in Opp. to Mot. to Dismiss 30.)

Amerisource, apparently misunderstanding the Government's position, argues it cannot be liable for failing to document its suspicion-dispelling investigations because "federal law has never imposed recordkeeping duties related to suspicious order reporting." (Mem. in Supp. of Mot. to Dismiss 41.) At oral argument, Amerisource said it believed the Government sought to hold it liable

Because the orders flagged under all of these systems met the definition of suspicious and Amerisource allegedly failed to either report them or dispel their suspicion, the Government states a claim that Amerisource violated its reporting obligations. 21 U.S.C. § 842(a)(5); U.S.C. § 832(a)(3); 21 C.F.R. § 1301.74(b).

3

i

The fourth category of Amerisource's alleged CSA violations concerns orders that triggered only one of ROMP's thresholds. A distributor must "discover" suspicious orders before it is required to report them. *See* U.S.C. § 832(a)(3); 21 C.F.R. § 1301.74(b). The Government alleges that Amerisource discovered these orders because it "specifically identified those orders as statistically unusual based on their size or pattern." (Mem. in Opp. to Mot. to Dismiss 31.) Amerisource responds that because ROMP did not flag these orders for human review, Amerisource did not "discover" these orders and was not obligated to report them. (Mem. in Supp. of Mot. to Dismiss 38.)

But "discovered" is defined more broadly than Amerisource believes, and for good reason. An order has been "discovered to be suspicious" when a distributor "has *obtained information* that an order is suspicious." *In re Masters Pharm.*, 80 Fed. Reg. at 55478 (emphasis added). A distributor violates the reporting requirement if it "chooses to ignore that information and fails to report the order." *Id.* And while Amerisource raises this argument in its motion to dismiss, determining whether an

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for failing to maintain documentation of its suspicious order investigations, confirming the misunderstanding. (Sept. 19, Tr. of Oral Arg. 125:22-126:20.) It clarified that it only objects to the idea that failure to keep these records can be "a violation [of the CSA] in and of itself," not to the records' ordinary evidentiary significance. (*Id.* 126:16-127:16.) (Recognizing the difference between "evidence and a charge" and asking the Court to recognize this distinction).

order has been discovered "involve[s] questions of fact that will necessarily depend on the totality of individual circumstances." *In re Nat'l Prescription Opiate Litig.*, 2019 U.S. Dist LEXIS 140020, at *72 n.8

ii

Since orders that triggered only one of ROMP's thresholds satisfy the statutory definition of suspicious, *see infra* subsection IV.B.2.ii, Amerisource was obligated to either report these orders or dispel their suspicion as long as it "discovered" them. 21 U.S.C. § 832(a)(3); 21 C.F.R. § 1301.74(b). The Complaint plausibly alleges it did.

The Government also contends Amerisource received orders which triggered only one of ROMP's thresholds, rather than the requisite two needed for the system to flag an order. (Compl. ¶¶ 486-89.) It further claims specific orders satisfying only one threshold were shipped to customers without being flagged for review or reported. (*Id.* ¶¶ 490-502), and that ROMP "identified" these orders. (Compl. ¶¶ 187, 491, 495, 499, 501). In its brief and at oral argument, the Government clarified what it meant by "identified."

In its brief, the Government explained that Amerisource allegedly "recognized and recorded each time an order breached a single algorithmic threshold indicating unusual size or pattern, but despite that recognition and recording, [] chose not to even hold the suspicious orders for human review." (Mem. in Opp. to Mot. to Dismiss 31-32.) Amerisource's automatic processing of these orders, the Government argues, "does not alter the fact that [it] 'obtained information' that the orders were unusual and thereby suspicious." (*Id.* at 32) (quoting *In re Masters Pharm.*, 80 Fed. Reg. at 55478).

At oral argument, the Government further stated it believes ROMP "recorded" orders breaching only one threshold and "identified [them] as unusual," even though it did not hold such orders for human review. (Sept. 19, Tr. of Oral Arg. 77:23-78:16.) Orders underpinning these allegations, the Government confirmed, were "caught" by Amerisource's SOMS. (*Id.* at 78:22-79:1). At this stage, the Government has sufficiently alleged that Amerisource "discovered," these orders.

4

i

The remaining category of Amerisource's alleged CSA violations pertains to orders Amerisource allegedly failed to report after receiving notice that the ordering customers were likely diverting controlled substances. Amerisource argues, primarily relying on *City of Huntington v. AmerisourceBergen Drug Corp.*, 609 F. Supp. 3d 408, that because the CSA and its implementing regulations only require distributors to report specific orders and do not include a category of "suspicious customers[s]," the Government is watering down its burden to "prove liability on an order-by-order basis." (Mem. in Supp. of Mot. to Dismiss 45.)

Distributors, however, cannot ignore information "that raises a suspicion not only with respect to a specific order, but also as to the legitimacy of a customer's business practices." *In re Masters Pharm.*, 80 Fed. Reg. at 55478. A customer pharmacy's "business model, dispensing patterns, or other characteristics might make an order suspicious," even if that order does not display unusual size, pattern or frequency. *Id.* at 55477 (quotations omitted).

For instance, DEA has found orders suspicious in part "because the pharmacy was buying an unusual mix of controlled and non-controlled substances, dominated overwhelmingly by controlled substances, which was not consistent with what legitimate pharmacies typically ordered." *Masters*, 861 F.3d at 221 (citing *Southwood*, 72 Fed. Reg. at 36497, 36501-02). Orders may also be suspicious in part because a distributor's agent visits a pharmacy and sees evidence "suggesting that the pharmacy [is] filling . . . illegitimate prescriptions." *Id.* (quoting *Southwood*, 72 Fed. Reg. at 36501) (internal quotation marks omitted). Other indicia include "an unusually high percentage" of a pharmacy's customers paying for controlled substances with cash. *Id.* at 220; *In re Masters Pharm.*, 80 Fed. Reg. at 55488.

Allowing distributors to ignore their customers' illegitimate business practices would "ill-serve[] the CSA's purpose" of preventing the illegal distribution, possession and improper use of controlled substances. *Masters*, 861 F.3d at 221 (quoting *In re Masters Pharm.*, 80 Fed. Reg. at 55473) (cleaned up). If a distributor has actual knowledge, much less suspicion, that a customer is diverting controlled substances, it makes little sense to excuse that distributor from either investigating or reporting these customers' orders just because they do not cleanly fit within any of Sections 802(57) and 1301.74(b)'s "exemplary rather than exhaustive" criteria. *Masters*, 861 F.3d at 221.

Moreover, *Huntington* did not abrogate the rule that orders can qualify as suspicious when customer pharmacies' business practices lack legitimacy. *Huntington* addressed a "single cause of action," a public nuisance allegation, against three distributors: Amerisource, Cardinal Health, Inc., and McKesson Corporation. 609 F.

Supp. 3d at 413-14. The plaintiffs, a West Virginia city and county, alleged that the distributors caused a public nuisance by creating an epidemic through their wholesale distribution of opioids. *Id.* at 413. The court concluded, among other things, that the plaintiffs could not prevail on a public nuisance claim predicated on product distribution[11] and failed to prove the distributors' conduct proximately caused their injuries. *Id.* at 471-82. Its analysis relied on principles of state law. *See id.* at 471-75. And rather than resolving these issues at the motion to dismiss stage, the court made its findings after a ten-week bench trial. *See id.* at 412.

Amerisource relies primarily on a portion of the *Huntington* decision that found the plaintiffs' expert witness' methods unpersuasive. *Id.* at 438-39. Specifically, the court concluded that these methods "were not convincing ways to achieve accurate results of the number of orders that should have been flagged or blocked." *Id.* at 439. The court found one of these methods unpersuasive for two reasons. First, the expert assumed that "for every single order" flagged by any of the expert's methods, "no due diligence was done to clear the suspicion." *Id.* at 441. Second, one of the methods "employ[ed] an assumption that once an order [was] flagged, all future orders [were] permanently and automatically to be flagged as suspicious as well." *Id.* Together, the court concluded, these assumptions meant that "after the flagging criteria [was] met once, [this method] deem[ed] every subsequent order suspicious and unable to be shipped (in perpetuity)." *Id.*

But the Government's allegations in this case differ from the expert methods discussed in *Huntington*. The Government alleges that Amerisource's customers'

[11] The court also rejected the plaintiffs' more expansive interpretation of "diversion" by favorably citing to *In re Masters Pharm*, *Masters*, and *Southwood*, as examples of "the kind of diversion against which distributors must guard." *Id.* at 477-80.

business practices were suspicious, which created a risk that those customers were diverting drugs Amerisource sent them. It does not assert that every single order from a given customer was suspicious merely because that customer had filed one suspicious order in in the past. Additionally, the Government does not assume that orders from these customers were irredeemably suspicious. It specifically alleges that Amerisource failed to either report these orders *or* dispel their suspicion.

ii

The Government plausibly alleges that Amerisource failed to report orders that were suspicious because it had received notice "that the customer[s] placing the order[s] [were] potentially facilitating the diversion of controlled substances." (Compl. ¶ 274.) For instance, the Government accuses Amerisource of refusing to report orders from what it labels "Pharmacy 2" as suspicious despite an outside auditor, sent by CSRA to conduct a site visit, reporting that the pharmacy's "due diligence procedures [were] insufficient" and that "the pharmacist in-charge did not appear to understand her legal obligations and that 50% of the pharmacy's controlled-substance sales were for oxycodone." (*Id.* ¶¶ 354-56, 358.)

Similarly, the Complaint alleges that Amerisource failed to report as suspicious orders from a customer described as "Pharmacy 3" despite finding its "business practices and ordering activities to be so suspicious that they warranted terminating Pharmacy 3 as a controlled-substance customer." (*Id.* ¶ 381.) Specifically, the Government alleges Amerisource received notice from CSRA's outside auditor that drug deals were occurring in the pharmacy's parking lot and that the pharmacist-in-charge

had admitted that the pharmacy provided controlled substances to individuals with prescriptions that no other pharmacies would fill. (*Id.* ¶¶ 371, 375.)

The Complaint also alleges Amerisource failed to report as suspicious orders from a customer referred to as "Pharmacy 4" despite the CSRA's determination that the pharmacy was selling "37% of its prescriptions for cash," and an outside auditor finding that it was responsible for "commonly abused/diverted controlled substances" and that "hand-to-hand exchanges" were occurring in the pharmacy parking lot. (*Id.* ¶¶ 389-90, 392, 394, 401.)

Finally, the Government claims a CSRA employee found that another customer, "Pharmacy 5," saw "large percentages of customers paying for controlled substances in cash" and "significant numbers of customers receiving combinations of controlled substances that are known to be dangerous and used for illegitimate purposes." (Compl. ¶ 418). The Government further alleges that Amerisource failed to report suspicious orders from Pharmacy 5 even though an outside auditor the CSRA sent to conduct a site visit "confirmed the already-identified red flags and found new ones," and informed senior CSRA management that "Pharmacy 5 was a mess and that its pharmacist would fill anything." (*Id.* ¶¶ 419-20, 428-29.) And the Government alleges that in many instances, Amerisource contacted the pharmacies and told them it would suspend business with them, but then "reversed course" and continued filling orders for these pharmacies without reporting to DEA or investigating the pharmacies further. (*Id.* ¶¶ 328-37, 377-83, 395-99, 421-23, 428-29.)[12] The Complaint plausibly alleges

[12] Amerisource argues the Government failed to allege facts sufficient to state a claim with respect to thousands of orders the Complaint does not specifically detail. (Mem. in Supp of Mot. to Dismiss 46-49.) The Court disagrees. The Government specifically alleges examples of what it claims to be illegal conduct by Amerisource. (Compl. ¶¶ 275-76.) Amerisource claims not to seek

Amerisource failed to report suspicious orders as required by the CSA and Section 1301.74(b). 21 U.S.C. § 842(a)(5); U.S.C. § 832(a)(3); 21 C.F.R. § 1301.74(b).

V

Finally, Amerisource contends that it cannot be liable for civil penalties for any violations of the reporting requirement occurring before the SUPPORT Act took effect on October 24, 2018. Prior to the SUPPORT Act's enactment, the suspicious order reporting requirement was imposed only by regulation. 21 C.F.R. § 1301.74(b). The SUPPORT Act, in relevant part, codified the reporting requirement and definition of "suspicious order," in the CSA, which now expressly requires distributors to "design and operate a system to identify suspicious orders" and report them "upon discover[y]." 21 U.S.C. §§ 802(57), 832. Amerisource believes that, prior to the SUPPORT Act's amendment of the CSA, any alleged violations of Section 1301.74(b) of the regulations were not violations of the CSA and that the Government cannot seek civil penalties for

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dismissal of allegations regarding orders from these named pharmacies "based upon either the Government's failure to allege that [Amerisource] discovered these orders to be suspicious or failure to plead in conformity with Rule 8." (Mem. in Supp of Mot. to Dismiss 48 n.22). This disclaimer, however, is inconsistent with Amerisource's proffered interpretation of its suspicious order reporting obligations and its argument that the Government cannot rely on a "suspicious customer" theory. (Mem. in Supp of Mot. to Dismiss 45-46.) The Court accordingly relies on these examples to demonstrate why the Government's allegations do not "fail[] as a matter of law." (*Id.* at 56.)

Additionally, the Complaint's references to, for example "many thousands of analogous orders," or "numerous occasions," (Compl. ¶¶ 432, 472), satisfy Rule 8. The Complaint's detailed factual allegations, designated as exemplary, alongside its references to similar and analogous instances, are "sufficient to justify moving the case beyond the pleadings." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 234-35 (3d Cir. 2008). The Government has alleged "enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element." *Id.* at 234 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). Rule 8 "does not require detailed allegations as to each individual" alleged violation because "[it]t is sufficient that [the defendant] has fair notice of the generalized conduct." *See PNC Bank, N.A. v. Republic Mortg. Ins. Co*, No. 2:12-cv-1470, 2013 WL 2285982, 2013 U.S. Dist. LEXIS 72872, at *11-12 (W.D. Pa. May 23, 2013). Providing "detailed examples of each category" of violations is sufficient under Rule 8 because defendants "will have the opportunity during discovery to develop the record regarding each individual" alleged violation." *Id.* at *12-13.

failure to report suspicious orders before October 24, 2018. The Government interprets Section 842(a)(5) of the CSA to allow it to seek civil penalties for failure to report suspicious orders under the regulations because those reports are "required under this subchapter." 21 U.S.C. § 842(a)(5). The Government believes accordingly that Amerisource's alleged violations of the pre-SUPPORT Act's regulations subject Amerisource to civil penalties.

Amerisource has the better of the argument. The CSA, prior to the SUPPORT Act's enactment, did not explicitly authorize the Attorney General or DEA to seek penalties for violations of Section 1301.74(b)'s reporting requirement. And no provision of the CSA, prior to the addition of Section 832, established a duty to report suspicious orders or any other duty broad enough to encompass Section 1301.74(b)'s reporting requirement. Violations of Section 1301.74(b) before the SUPPORT Act's effective date were therefore not violations of any provision of the CSA for which the Government may seek civil penalties.

A

While administrative agencies enjoy wide discretion in explaining and enforcing statutes by promulgating regulations, "[they] may decide to penalize specific kinds of conduct only when Congress has expressly delegated that power to [them]." *Groves v. Modified Ret. Plan for Hourly Paid Emps. of Johns Manville Corp. & Subsidiaries*, 803 F.2d 109, 117 (3d Cir. 1986); *see also United States v. Eaton*, 144 U.S. 677, 686-88 (1892); *Loving v. United States*, 517 U.S. 748, 768 (1996) (agencies may "define[] by regulation what conduct will be criminal, so long as Congress makes the violation of regulations a criminal offense and fixes the punishment, and the regulations confine

themselves within the field covered by the statute") (quotations omitted) (cleaned up). In other words, agencies can only penalize conduct when Congress has expressly authorized them to. *See, e.g.*, *United States v. Grimaud*, 220 U.S. 506, 519 (1911) ("any violation of the provisions of this act *or such rules and regulations of the Secretary* shall be punished as prescribed in section 5388") (emphasis added). This principle applies in the civil as well as the criminal context when the civil provision is penal rather than remedial. *Groves*, 803 F.3d at 117 ("while an administrative agency has wide discretion in deciding how to implement remedial legislation . . . it may decide to *penalize* specific kinds of conduct only when Congress has expressly delegated that power to the agency") (emphasis added).[13]

Section 842(a)(5) is penal. In *Groves*, the court found an ERISA provision imposing civil penalties on plan administrators to be penal even though the statute provided that these penalties would be paid to complaining plan participants. *Id.* The court acknowledged the scheme's remedial component but concluded "that the threat of personal liability was imposed primarily because of the effect it would have on a plan administrator -- inducing him to comply with the statute -- and only secondarily, if at all, out of a desire to make participants whole." *Id.* Section 842(a)(5) imposes civil penalties but does not include an analogous remedial component. Unlike in *Groves*, the

[13] Other examples include a penalty provision of the Securities Exchange Act of 1934, which states that "any issuer which fails to file information, documents, or reports required to be filed under subsection (d) of section 15 of this title *or any rule or regulation* thereunder shall forfeit to the United States the sum of $100 for each and every day such failure to file shall continue," 15 U.S.C. § 78ff(b) (emphasis added); the Marine Protection, Research and Sanctuaries Act's penalty provision, which renders "any person who violates any provision of this title, *or of the regulations promulgated under this title* . . . liable to a civil penalty" 33 U.S.C. § 1415(a) (emphasis added); and the Occupational Safety and Health Act's penalty provision, which authorizes civil penalties for employers who violate "Section 5 of this Act, any standard, rule, or order promulgated pursuant to Section 6 of this Act, *or regulations prescribed pursuant to this Act*." 29 U.S.C. § 666(a) (emphasis added).

Court is therefore not presented with the "close question" of whether a penal or remedial purpose predominates. *See id*.

While Section 842(a)(5) authorizes civil penalties, "its prohibitory effect is quasi-criminal" because the penalties it imposes "although civil in description, are penal in character." *Clinical Leasing Serv., Inc.*, 925 F.2d at 122 & n.2 (considering Sections 822(e) and 842(a)(2).

B

The Government believes Section 842(a)(5)'s reference to "this subchapter" includes the regulations. Section 842(a)(5), it argues, "was drafted broadly to sweep in *any and all failures*, by *any person*, to comply with *any* one of the [CSA's] recordkeeping and reporting requirements." (Mem. in Opp. to Mot. to Dismiss 49) (emphasis in original). Again, as a general rule, Congress must expressly delegate the power to penalize such failures. *Groves*, 803 F.3d at 117; *Grimaud*, 220 U.S. at 519; *United States v. Seelig*, 622 F.2d 207, 210-11 (6th Cir. 1980).

Even if an implied delegation of this power were permissible, Section 842(a)(5) does not contain one. The Government contends when the CSA was passed, Congress "gave the Attorney General a central role in effectuating the statute through *broad delegations of authority* to flesh out the details of the statutory obligations through regulations." (Mem. in Opp. to Mot. to Dismiss 48) (emphasis added). It points to separate provisions of the CSA to support its argument. Section 821 authorizes the Attorney General "to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals." 21 U.S.C. § 821. And Section 871(b)

gives the Attorney General power to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this title." 21 U.S.C. § 871(b). But these provisions do not broadly authorize the Attorney General to "flesh out" all of the CSA's myriad other requirements. *Gonzales v. Oregon*, 546 U.S. 243, 258-59, 264-65 (2006). They instead "give[] the Attorney General limited powers, to be exercised in specific ways." *Id.* at 259. They do not "delegate to the Attorney General authority to carry out or effect all provisions of the CSA." *Id.* If these provisions grant the Attorney General limited rather than plenary authority, Section 842(a)(5) cannot be read to allow the Attorney General to indirectly expand this authority and decide what conduct violates the CSA. *See id.* at 260-65.[14]

The Government also emphasizes that the DEA has "maintained for many years" that civil penalties were available for failure to file suspicious order reports required by regulation, and pre-SUPPORT Act amendments to Section 842 did not disclaim these

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[14] The Government also argues that unless Section 842(a)(5)'s reference to "this subchapter" categorically includes regulations, the provision's references to notifications and declarations would be rendered meaningless. (Mem. in Opp. to Mot. to Dismiss. 51.) But the original CSA makes it unlawful to import certain controlled substances into the United States unless such substance is "imported pursuant to such notification or declaration requirements as the Attorney General may by regulation prescribe," or the importer has "lawfully obtained such substance and [] makes such declaration (or gives such other notification) as the Attorney General may by regulation require." Pub. L. No. 91-513, 84 Stat. 1236, 1285-86, 1288 §§ 1002(b)(2), 1006(a).

Similarly, Section 843(a)(4)(A) of the CSA prohibits furnishing false or fraudulent material information in reports "required to be made, kept, or filed under this subchapter." 21 U.S.C. § 843(a)(4)(A). The Government argues that applying a similarly narrow construction of "this subchapter" to Section 843 would create a loophole, prohibiting falsity only in reports required by statute and not by regulation. (Mem. in Opp. to Mot. to Dismiss 49-50.) But violating these regulations would also violate Section 827, which requires records to be "in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General." 21 U.S.C. § 827(b). Violating such regulations would violate Section 843(a)(4)(A) so long as those regulations "confine themselves within the field covered by the statute." *Loving*, 517 U.S. at 768 (quoting *Grimaud*, 220 U.S. at 518.)

interpretations. (Mem. in Opp. to Mot. to Dismiss 56.) Therefore, it argues, Congress "endorsed and adopted this understanding." (*Id.*) "[W]hen Congress revisits a statute giving rise to a longstanding administrative interpretation without pertinent change," the Government argues, "the congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress." *CFTC v. Schor*, 478 U.S. 833, 846 (1986) (quotations omitted).

Any inferences, however, regarding Congress' intentions in leaving Section 842(a)(5) unchanged are not dispositive of the analysis. "[S]peculation about why a later Congress declined to adopt new legislation offers a particularly dangerous basis on which to rest an interpretation of an existing law a different and earlier Congress did adopt. *Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1747 (2020) (quotations omitted) (sex discrimination includes discrimination based on homosexuality and transgender status even though "Congress ha[d] considered several proposals" to expand Title VII's list of protected characteristics and declined to do so).[15]

C

1

This does not mean, however, that violating regulations can never violate the CSA. If a regulation imposes a duty that a statutory provision has already established, the violation of that regulation violates the statute. *See, e.g.*, *Abramski v. United*

[15] The Government also notes past cases in which parties "agreed . . . to settle claims or potential claims for civil penalties" for failing to report, pursuant to Section 1301.74(b), suspicious orders of controlled substances. *In re Masters Pharm.*, 80 Fed. Reg. at 55422 (quotations omitted) (cleaned up). The Court can't take much from that. Parties settle cases for any number of reasons, including to attain the certainty of a resolution as opposed to the vagaries of litigation. The few other decisions that reference settlements of claims for civil penalties for violations of Section 1301.74(b) did so without considering the scope of Section 842(a)(5). *See, e.g., Stanley v. Arnold*, No. 1:12-cv-482, 2012 WL 5269147, 2012 U.S. Dist. LEXIS 152096, at * 6-7 (S.D. Ohio Oct. 23, 2012).

States, 573 U.S. 169, 191-92 (2014). But the statute, rather than the regulation alone, must impose the duty.

In *Abramski v. United States*, a case the Government relies on, the defendant argued that he could not be convicted of knowingly making a false statement "with respect to the information required by this chapter to be kept in the records of a federally licensed dealer," because the false statement he was charged with making—that he was buying a firearm for himself rather than someone else—was not information explicitly required by a statutory provision. *Id.* at 191-92 (quoting 18 U.S.C. § 924(a)(1)(A)). Instead, federally licensed dealers were only required by *regulation* to retain forms filled out in the course of sales. *Id.* at 192. Therefore, the defendant argued, his false statement did not appear on a form required by "this chapter," since the regulation, not the statute, required the information to be kept on the form. *Id.* at 191-92.

The Supreme Court rejected this argument because another statutory provision required dealers to "maintain such records of . . . sale, or other disposition of firearms at [their] place[s] of business for such period, and in such form, as the Attorney General may by regulations prescribe." *Id.* at 192 (quoting 18 U.S.C. §923(g)(1)(A)). Because Section 923(g)(1)(A) required dealers to retain records mandated by regulation, the information the regulation required was information "required by this chapter" to be kept in dealers' records, and making false statements on that form violated Section 924(a)(1)(A). *Id.* at 191-92. *Abramski* does not support the Government here. The regulation in that case specified an already-existing statutory duty, while Section 1301.74(b) does not.

In *Groves*, the Third Circuit held that civil penalties could not be imposed for the violation of a regulation implemented pursuant to ERISA. 803 F.2d at 116-19. A provision of that statute imposed personal liability upon any ERISA plan administrator who failed or refused to comply with a participant's request for any information that they were required "by this subchapter" to provide. *Id.* at 114 (quoting 29 U.S.C. § 1132(c) (1985)). The regulation required plan administrators to explain the reasons for denying applications for disability benefits. *Id.* at 113.

The court held that violating the regulation did not violate the statute because no ERISA provision "had explicitly [prohibited] violations of agency regulations." *Id.* at 118 (citing *Seelig*, 622 F.2d at 210). The statutory provision closest to doing so stated that "[i]n accordance with regulations of the Secretary, every employee benefit plan shall provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial." *Id.* at 113 n.2 (quoting 29 U.S.C. § 1133(1) (1985)). This provision, "by its terms [spoke] only of the disclosure obligations of [ERISA Plans]," and did not authorize the Secretary "to impose any obligations on the plan administrator." *Id.* at 118. In other words, no statutory provision created the duty imposed by the regulation, and the regulation's mandate was thus not required "by this subchapter." *Id.* Critically absent was statutory language "grant[ing] the Secretary of Labor the power to decide that plan administrators' conduct is to be penalized." *Id.*

In *United States v. Seelig*, the Sixth Circuit Court of Appeals addressed regulations implemented pursuant to Section 841(a)(1) of the CSA. 622 F.2d at 209-11. Section 841(a)(1) prohibited the knowing or intentional distribution and dispensing of

controlled substances "[e]xcept as authorized by this subchapter (The Controlled Substances Act)." *Id.* at 210. The defendant pharmacists had been charged with violating a regulation prohibiting the distribution, without a prescription, of over four ounces of a prescription cough medicine in the span of 48 hours. *Id.* at 209. They argued that selling the medicine violated only the regulation and not the CSA itself because the CSA did not expressly "make violations of the regulations criminal," and "the Attorney General, who promulgates the regulations, does not have the authority to expand the criminal liability determined by Congress in the statute." *Id.*

Section 829(c) prohibits dispensing or distributing Schedule V drugs "other than for a medical purpose." 21 U.S.C. § 829(c). The pharmacists argued that as long as they dispensed the medicine for such a purpose, they were doing so "as authorized by this subchapter." *Id.*; *Seelig*, 622 F.2d at 210.

The court rejected this argument, finding that the CSA did "expressly, albeit in a convoluted fashion," provide that dispensing in violation of the regulations was not authorized by this subchapter. *Id.* at 210-11. The court pointed to Section 822(b) of the CSA, which stated that "persons registered by the Attorney General under this subchapter" were authorized to distribute controlled substances "to the extent authorized by their registration and in conformity with the other provisions of this subchapter." *Id.* at 210 (quoting 21 U.S.C. § 822(b)). Therefore, Sections 822(b) and 829(c), in combination, required pharmacists to dispense or distribute Schedule V drugs "for a medical purpose *and* to be within the authority of their registration as determined by the Attorney General." *Id.* (emphasis added). Consequently, violating

the regulation meant that the pharmacists did not dispense or distribute the medicine "as authorized by this subchapter" as Section 841(a)(1) required. *Id.* at 210-11.[16]

While the court noted that Sections 821 and 871(b) of the CSA authorized the Attorney General to promulgate regulations relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and "promulgate and enforce rules, regulations, and procedures that he deems necessary for the efficient execution of his functions," *id.* at 210, this general grant of authority was not enough. Otherwise, the court would have had no need to discuss the interaction between Sections 822(b) and 829(c).

Similarly, in *Groves*, the court recognized that the regulation was validly promulgated pursuant to another ERISA provision authorizing the Secretary to promulgate "such regulations as he finds necessary or appropriate to carry out the provisions of' subchapter I of ERISA." *Groves*, 803 F.2d at 118 n.10 (quoting 29 U.S.C. § 1135 (1985)). Nevertheless, it concluded that no statutory provision sufficiently authorized the Secretary to penalize violations of the regulation. *Id.* at 118-19. So too here.

2

Section 842(a)(5)'s reference to "this subchapter," only encompasses regulatory violations that also violate another specific provision of the CSA. Section 842(a)(5) does

[16] When violating regulations also violates Sections 822 or 829 of the CSA, that conduct is not "authorized by this subchapter," under Section 841(a)(1). *See, e.g.*, *Ruan v. United States*, 142 S. Ct. 2370, 2374-75 (2022) (violating 21 C.F.R. § 1306.04(a) violates Section 841(a); *Gonzales*, 546 U.S. at 279 (Section 1306.04(a) of the regulations interprets requirements codified in Section 829); *see also United States v. Goodman*, No. 22-435, 2023 WL 5672834, 2023 U.S. Dist. LEXIS 155058, at *5 (E.D. Pa. Sept. 1, 2023) ("Registrants can only distribute Schedule II, III, and IV controlled substances upon a prescription. 21 U.S.C. § 829(a), (b). The CSA's implementing regulations clarify that a prescription is effective only if it is 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)").

not impose its own reporting requirements. Instead, it expressly makes it unlawful to refuse or negligently fail to make reports required elsewhere by the CSA. For instance, Sections 827 requires distributors to make periodic reports to the Attorney General, in the times and forms the Attorney General requires, of "every sale, delivery, or other disposal" of "narcotic controlled substances." 21 U.S.C. § 827(d)(1). It further states that "[e]very inventory or other record required under this section shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General." 21 U.S.C. §§ 827(b)(1). Section 830, in relevant part, requires reporting of certain "proposed regulated transactions" involving listed chemicals. 21 U.S.C. § 830(b). Refusing or negligently failing to comply with them violates Section 842(a)(5). 21 U.S.C. § 842(a)(5).

For that reason, courts have consistently recognized that violations of other sections of the CSA, as well as regulations applying and explaining these sections, constitute violations of Section 842(a). *See, e.g.*, *United States v. Stidham*, 938 F. Supp. 808, 814-16 (S.D. Ala. 1996) (finding violations of regulations to constitute violations of Section 842(a)(5) because the defendant's conduct also violated Section 827); United *States v. Clinical Leasing Serv.*, 759 F. Supp. 310, 312-17 (E.D. La. 1990) (finding violations of various regulations to also violate Sections 827, 822, and 829 and therefore Section 842), *aff'd* 925 F.2d 120 (5th Cir. 1991).

These cases show that violating other recordkeeping or reporting requirements in different provisions of the CSA also violates Section 842(a)(5), because "this

subchapter," includes other CSA provisions.[17] But violating Section 1301.74(b) does not violate any of these other CSA provisions.

3

The SUPPORT Act codified the suspicious order reporting regime; it did not amend any reporting process in place already in the CSA. *See* Preventing Drug

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[17] Some courts have summarily reached contrary conclusions. *See, e.g.*, *United States v. Lerner*, No. 85 C 7593, 1986 WL 8471, 1986 U.S. Dist. LEXIS 22197, at *2-4 (N.D. Ill. July 28, 1986). The *Lerner* court, in relevant part, denied the defendant's motion to dismiss two counts of the Government's complaint. *Id.* at *4-5. One count alleged violations of Sections 822(b), which authorizes those registered to manufacture, distribute or dispense controlled substances to do so "to the extent authorized by their registration," and Section 822(e), which requires them to obtain separate registrations for each principal place of business where they manufacture, distribute or dispense controlled substances. *Id.* at *4; 21 U.S.C. § 822(b), (e). The court found that violating a regulation requiring storage facilities to be similarly registered also plausibly violated Section 822. *Lerner*, 1986 U.S. Dist. LEXIS 22197, at *4 ("Hence Count IV sufficiently alleges conduct regulated by *the Act*") (emphasis added).

The *Lerner* court also denied the defendant's motion to dismiss a count alleging violations of Sections 827(a)(3) and 842(a)(5). *Id.* Section 827(a)(3) requires registrants "manufacturing, distributing, or dispensing a controlled substance or substances [to] maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him." 21 U.S.C. § 827(a)(3). The court found that while neither Section 827(a)(3) nor Section 842(a)(5) explicitly required the defendant to report break-ins at a location where controlled substances were stored, a regulation did impose this duty. *Lerner*, 1986 U.S. Dist. LEXIS 22197, at *4. The court did not clarify whether it interpreted Section 827(a)(3), Section 842(a)(5), or both, to require this report. *Id.* It only cited *United States v. Lartey*, 716 F.2d 955 (2d Cir. 1983).

Lartey summarily stated that Section 843(a)(4)(A) of the CSA, which prohibits furnishing false or fraudulent material information in reports "required to be made, kept, or filed under this subchapter," 21 U.S.C. § 843(a)(4)(A), was violated when the defendant made a false statement on a form required by regulation. *Lartey*, 716 F.2d at 964-65. Neither *Lartey* nor *Lerner* acknowledged *Eaton*, *Grimaud* or *Seelig* or addressed the issue of whether the Attorney General could unilaterally render conduct unlawful under the CSA. And unlike those courts, this Court is bound by the Third Circuit's decision in *Groves*.

The Government also relies on *United States v. Tull-Abreu*, 921 F.3d 294 (1st Cir. 2019). There, the court, in a footnote, stated that a regulation required prescriptions to be "dated as of, and signed on, the day when issued." *Id.* at 304 & n.6 (quoting 21 C.F.R. § 1306.05(a)). The defendant had been charged with furnishing false information in violation of Section 843(a)(4)(A) by dating prescriptions with "dates on which they had not been signed." *Id.* at 299. The court was not confronted with the issue of whether requirements imposed solely by regulation were "required . . . under this subchapter," and did not discuss it. Moreover, other courts have found that violating this regulation also violates Section 829 of the CSA. *See, e.g.*, *United States v. Salcedo*, No. 02-1095, 2003 U.S. Dist. LEXIS 8562, at *3 (E.D.N.Y. Jan. 29, 2003) (explaining that violations of Section 1306.05(a) violate Section 829(a) and "[i]t is a violation of section 842 of the [CSA] to distribute Schedule II controlled substances in violation of the provisions of section 829(a)") (report and recommendation adopted in *United States v. Salcedo*, N0. 02-1095, 2003 WL 21196843, 2003 U.S. Dist. LEXIS 8561, at *3 (E.D.N.Y. Feb. 19, 2003).

Diversion Act of 2018, Pub. L. No. 115-271, 132 Stat. 3894, 3956-58 (2018) (adding 21 U.S.C. § 832). Prior to the SUPPORT Act's October 24, 2018, effective date, only the regulations, not the CSA, established a duty to report suspicious orders. As discussed, neither Sections 821 nor 871(b)'s general grants of authority can make violations of Section 1301.74(b) violations of the CSA itself. And the CSA's other pre-SUPPORT Act reporting requirements are not broad enough to include the duty to report suspicious orders.

Section 827(d)(1), for instance, requires distributors to make reports "of every sale, delivery, or other disposal" of narcotic controlled substances "at such time or times and in such form as the Attorney General may require." 21 U.S.C. § 827(d)(1). A few courts have implied or stated in passing that Section 827(d)(1) requires the reporting of suspicious orders. *See, e.g.*, *United States v. Four Hundred Sixty Three Thousand Four Hundred Ninety Seven Dollars & Seventy Two Cents ($463,497.72) in United States Currency*, 779 F. Supp. 2d 696, 709 (E.D. Mich. 2011) (Section 827(d)(1) requires suspicious order reporting); *City of Boston v. Purdue Pharma, L.P.*, No. 1884CV02860, 2020 Mass. Super. LEXIS 23, at *2-3 (Mass. Supp. Jan. 29, 2020) (referring to Section 827 without specifying a subsection).

But these courts do not explain why that is so or cite to any authority for such a proposition. Section 1301.74(b)'s suspicious order reporting requirement is broader than Section 827(d)(1)'s requirement to report sales, deliveries, or disposals of controlled substances. It "requires the reporting of an *order*," even if the order is "rejected entirely" and never shipped. *In re Masters Pharm.*, 80 Fed. Reg. at 55483 (emphasis in original). And "[w]here Congress does not furnish a definition of its own,

[courts] generally seek to afford a statutory term its ordinary or natural meaning." *HollyFrontier Cheyenne Ref., LLC v. Renewable Fuels Ass'n*, 141 S. Ct. 2172, 2176 (2021) (quotations omitted). "Delivery" is a specific term in the CSA[18] and the natural meaning of "sales" and "disposals" contemplates a transfer, rather than an offer to make a purchase. Moreover, Section 827(d)(1) also requires that these reports identify by registration number the person or establishment "to whom such sale, delivery, or other disposal was made," excluding mere order forms. 21 U.S.C. § 827(d)(1).

Section 827(b)(1) states that "[e]very inventory or other record required under this section shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General." 21 U.S.C. § 827(b)(1). At least one court has found Section 827(b)(1) to require registrants to report "any theft or significant loss of any controlled substances within one business day of discovery," a duty specified in 21 C.F.R. § 1301.74(c). *Stidham*, 938 F. Supp at 816.[19] Reading Section 827(b)(1) this way, however, would expand Section 827(d)'s reporting requirements beyond the statute's plain text and would give the Attorney General the power to require distributors to report mere orders, allowing it to ignore and even rewrite Section 821(d)(1) to require reports of things other than sales, deliveries and

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[18] "[D]eliver" or "delivery" means "the actual, constructive, or attempted transfer of a controlled substance or a listed chemical." 21 U.S.C. § 802(8). "Dispense" means "to deliver a controlled substance.," and "distribute" means "to deliver (other than by administering or dispensing) a controlled substance or listed chemical." *Id.* § 802(10)-(11). These terms all encompass the transfer or attempted transfer of controlled substances rather than the receipt of orders. *See, e.g.*, *United States v. Silva-De-Hoyos*, 702 F.3d 843, 848 (5th Cir. 2012) (a conviction for possession with intent to distribute is not an "offense consisting of the distribution of controlled substances," because it falls outside the scope of Section 802's definitions of "distribute" and "deliver") (quotations omitted).

[19] The court read Section 827(b) very broadly, also finding without explanation that the defendant violated this provision "by failing to properly secure methadone in the drug safe after clinic hours, which allowed for employee pilferage and diversion of methadone," rather than storing it in a safe or steel cabinet as required by regulation. *Id.* at 815.

disposals. 21 U.S.C. § 827(d)(1). These subsections separately refer to reporting and recordkeeping, and "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Alli v. Decker*, 650 F.3d 1007, 1012-13 (3d Cir. 2011) (quoting INS *v. Cardoza-Fonseca*, 480 U.S. 421, 432 (1987) (cleaned up). This principle also applies to disparities between subsections of the same provision. *Nken v. Holder*, 556 U.S. 418, 429-31 (2009); *Russello v. United States*, 464 U.S. 16, 23 ("We refrain from concluding here that the differing language in the two subsections has the same meaning in each"). Section 827(b)(1) accordingly also does not require suspicious order reporting.

Similarly, Section 828 requires "every person who in pursuance of an order required under subsection (a) *distributes a controlled substance* shall preserve such order for a period of two years, and shall make such order available for inspection and copying by officers and employees of the United States duly authorized for that purpose by the Attorney General." 21 U.S.C. § 828(c) (emphasis added). This provision requires distributors to preserve records of filled orders, not report suspicious orders like Section 1301.74(b) does. And Section 830 requires reporting of "proposed regulated transactions" involving listed chemicals, but not controlled substances. 21 U.S.C. § 830(b); *In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804, 2023 WL 3266877, 2023 U.S. Dist. LEXIS 79357, at *85 (N.D. Ohio May 5, 2023) (differentiating between controlled substances and listed chemicals).[20]

[20] Listed chemicals are products used in the manufacture of controlled substances. 21 U.S.C. § 802(33)-(35).

Finally, even if the Court could construe these various other CSA provisions broadly enough to impose a duty to report suspicious orders, the rule of lenity counsels against doing so. Under the rule, "penal statutes are to be construed strictly and an individual is not to be subjected to a penalty unless the words of the statute plainly impose it." *Bittner v. United States*, 143 S. Ct. 713, 724 (2023) (quotations omitted and emphasis removed). It applies when a grievous ambiguity or uncertainty remains even "after seizing everything from which aid can be derived." *Ocasio v. United States*, 578 U.S. 282, 295 n.8 (2016) (quotations omitted). In *Groves*, the court applied the rule to an ERISA provision because of the "substantial uncertainty regarding the relationship between the terms 'plan' and 'plan administrator,'" and "significant uncertainty as to whether violations of 'this subchapter' includes regulations of violations promulgated pursuant to 'this subchapter.'" *Groves*, 803 F.3d at 118.

When a statute "has not plainly and unmistakably established" that the violation of a regulation violates a statute, courts should "decline to interpret the penalty provision to embrace such violations." *Id.* at 118-19. The Court declines to do so here.

An appropriate Order follows.

BY THE COURT:

/s/ Gerald J. Pappert
GERALD J. PAPPERT, J.