

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

UNITED STATES OF AMERICA	)	
	)	Case No. 15 CR 339-1
v.	)	
	)	Hon. Amy J. St. Eve
DAVID STELMACHOWSKI	)	
	)	

**MEMORANDUM OPINION AND ORDER**

AMY J. ST. EVE, District Court Judge:

Defendant Stelmachowski has moved to dismiss Count One of the Superseding Indictment. (R. 86, 99.) For the following reasons, the Court denies his motion.

**BACKGROUND**

**I. The Superseding Indictment**

On November 16, 2017, a grand jury returned a twenty-five-count Superseding Indictment against David Stelmachowski and William Mikaitis. (R. 80.) According to Count One, under the Federal Food, Drug, and Cosmetic Act (the “Act”), “dispensing a prescription drug without a valid prescription by a licensed practitioner was deemed to be an act that resulted in the drug being misbranded while held for sale.” (*Id.* at 2.) Count One charges that Mikaitis, a physician, and Stelmachowski conspired to commit an offense against the United States in violation of 18 U.S.C. § 371 by dispensing or causing to be dispensed “prescription drugs without a valid prescription,” in turn causing said drugs to be “misbranded” in violation of 21 U.S.C. §§ 353(b)(1), 331(k), and 333(a)(2), sections of the Act. (*Id.* at 3, 26.)

Count One, in more detail, charges that Mikaitis issued over 620 prescriptions to Stelmachowski and an unnamed individual for Oxycodone, OxyContin, and Amphetamine Salt Combo, or Adderall, all of which are Schedule II Controlled Substances. (*Id.* at 1–3.) It alleges

that Mikaitis wrote these prescriptions “without performing a thorough physical examination or ordering medical tests” on Stelmachowski, and without “monitor[ing]” Stelmachowski’s and the unnamed individual’s use of the drugs. (*Id.* at 3–4.) Count One charges as overt acts hundreds of instances, over the course of three years, in which Stelmachowski “filled and caused to be filled” a prescription written by Mikaitis. (*Id.* at 4–26.) In total, Count One charges, Stelmachowski filled prescriptions for approximately 37,000 pills or tablets of the drugs. (*Id.* at 3.) Count One also alleges that Stelmachowski filled those prescriptions “at 80 different Chicago-area pharmacy locations to avoid attracting undue attention to the number of prescriptions and pills prescribed by” Mikaitis. (*Id.* at 3.) Stelmachowski and Mikaitis did this, according to Count One, with “intent to defraud or mislead,” in violation of Section 333(a). (*Id.*)

The Superseding Indictment further alleges that Stelmachowski and Mikaitis’s conduct constituted violations of the Controlled Substances Act. Specifically, it charges that Stelmachowski and Mikaitis conspired to acquire controlled substances by “misrepresentation, fraud, and deception” in violation of 21 U.S.C. § 846 (Count Two) (*id.* at 27); that Mikaitis “knowingly and intentionally distribute[d] a controlled substance . . . outside the usual course of professional practice and without legitimate medical purpose” in violation of 21 U.S.C. § 841(a) (Counts Three through Ten and Counts Nineteen through Twenty-Five) (*id.* at 28, 30); and that Stelmachowski “knowingly and intentionally possess[ed] with the intent to distribute a controlled substance” also in violation of 21 U.S.C. § 841(a) (Counts Eleven through Eighteen) (*id.* at 29).

## **II. The Food, Drug, and Cosmetic Act**

The Act prohibits the misbranding of prescription drugs. That prohibition, as it is relevant to this case, lies in two provisions of the Act—Sections 353(b)(1) and 331(k) (together,

the “Misbranding Statutes”). Section 353(b)(1) states that any prescription drug or drug “not safe for use except under the supervision of a practitioner” (a “covered drug”):

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist.

21 U.S.C. § 353(b)(1). Section 353(b)(1) therefore protects the dispensing of a covered drug upon a “prescription” or a refilling upon “authorization”—but otherwise, “[t]he act of dispensing a [covered] drug” is “an act which results in the drug being misbranded while held for sale.” *Id.* While Section 353(b)(1) describes conduct that causes a drug to be misbranded, Section 331(k) criminalizes such conduct. It prohibits “any . . . act” to a drug that “results in such an article being . . . misbranded.” 21 U.S.C. § 331(k). The Act also provides that any person who violates Section 331 “with the intent to defraud or mislead” faces three years imprisonment and a fine of no more than \$10,000. 21 U.S.C. § 333(a)(2).

### **LEGAL STANDARD**

A defendant may “raise by pretrial motion any defense, objection, or request that the court can determine without a trial on the merits.” Fed. R. Crim. P. 12(b)(1); *see also* Fed. R. Crim. P. 12(b)(3)(A)(v) (requiring motions regarding “an error in the grand-jury proceeding” to be filed via pretrial motion); Fed. R. Crim. P. 12(b)(3)(B)(v) (requiring the same for motions regarding an indictment’s “failure to state an offense”). When considering a motion to dismiss, a court must view all allegations as true and in the light most favorable to the government. *See United States v. Yashar*, 166 F.3d 873, 880 (7th Cir. 1999); *United States v. Moore*, 563 F.3d 583, 586 (7th Cir. 2009). A court must also review indictments “on a practical basis and in their

entirety, rather than in a hypertechnical manner.” *United States v. Cox*, 536 F.3d 723, 726 (7th Cir. 2008).

## ANALYSIS

Defendant Stelmachowski argues that the Court should dismiss Count One, which alleges a conspiracy to violate the Misbranding Statutes, for three alternative reasons: (1) because it fails to state a claim; (2) because the government erred in instructing the grand jury on what “prescription” means under Section 353(b)(1); and (3) because the Misbranding Statutes are unconstitutionally vague. Each argument, however, rests on the same predicate contention—that “prescription,” as that term is used in Section 353(b)(1), should include the more than 620 alleged prescriptions written by Mikaitis, prescriptions which, according to the Superseding Indictment, were fraudulent and facilitated a drug conspiracy. The Court disagrees.

### **I. Count One of the Superseding Indictment Sufficiently States a Claim**

Defendant Stelmachowski first submits that Count One fails to state a claim. Federal Rule of Criminal Procedure 12(b)(3)(B) allows a defendant to make a pretrial motion that challenges the sufficiency of the indictment. *See United States v. Boender*, 691 F. Supp. 2d 833, 837 (N.D. Ill. 2010). A defendant may challenge the indictment’s sufficiency by arguing that it fails to state an offense. Fed. R. Crim. P. 12(b)(3)(B)(v). Federal Rule of Criminal Procedure 7(c)(1) requires an indictment to “be a plain, concise, and definite written statement of the essential facts constituting the offense charged.” Fed. R. Crim. P. 7(c)(1).

The Seventh Circuit has explained that an indictment is sufficient where it (1) states the elements of the crimes charged, (2) adequately informs the defendant of the nature of the charges brought against him, and (3) enables the defendant to assert the judgment as a bar to future prosecutions for the same offense. *See United States v. Vaughn*, 722 F.3d 918, 925 (7th Cir.

2013); *see also United States v. Gerebizza*, --- Fed. Appx. ---, 2017 WL 6540505, at \*3 (7th Cir. Dec. 21, 2017) (stating the same standard). “To successfully challenge the sufficiency of an indictment, a defendant must demonstrate that the indictment did not satisfy one or more of the required elements and that he suffered prejudice from the alleged deficiency.” *Vaughn*, 722 F.3d at 925; *see also United States v. Castaldi*, 547 F.3d 699, 703 (7th Cir. 2008). A court may dismiss an indictment, or a portion of one, if its allegations do not state a violation of the governing statute. *See United States v. Hollnagel*, No. 10 CR 00195, 2011 WL 3664885, at \*8 (N.D. Ill. Aug. 19, 2001) (citing *United States v. Risk*, 843 F.2d 1059, 1061 (7th Cir. 1988)).

In this case, Stelmachowski argues that because Section 353(b)(1) protects the dispensing of a covered drug pursuant to a “prescription,” and because the Superseding Indictment states that he had prescriptions—albeit allegedly fraudulent ones—for the transactions at issue, Count One does not state a claim. The issue before the Court thus turns on the definition of “prescription” under the Act, and more precisely, whether the allegedly fraudulent prescriptions described in the Superseding Indictment fall under that definition.

**A. The plain language and ordinary meaning of “prescription” exclude the fraudulent prescriptions alleged in the Superseding Indictment**

“The cardinal rule of statutory interpretation is that courts must first look to the language of the statute and assume that its plain meaning accurately expresses the legislative purpose.” *United States v. Miscellaneous Firearms, Explosives, Destructive Devices & Ammunition*, 376 F.3d 709, 712 (7th Cir. 2004); *accord United States v. Turner*, 836 F.3d 849, 861 (7th Cir. 2016) (“We start by examining the language of the statute and regulations underlying [the] offense.”). The relevant language of Section 353(b)(1) states that a covered drug “shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to

administer such a drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist . . . .” 21 U.S.C. § 353(b)(1)(B).

As an initial matter, Stelmachowski submits that Congress gave “extensive definition” to “prescription” within Section 353(b)(1) itself, and because that “extensive definition” did not exclude fraudulent prescriptions, they must fall within the definition. (R. 86 at 9–10; *see also* R. 99 at 3.) The Court disagrees. Congress did not define “prescription” in Section 353(b)(1), as several courts have recognized. *See United States v. Smith*, 573 F.3d 639, 651 (5th Cir. 2009) (“The text of the statute provides limited clarity as to the parameters of ‘prescription,’ as it is not explicitly defined.”); *United States v. Riccio*, 43 F. Supp. 3d 301, 308 (S.D.N.Y. 2014) (“the statute provides no definition for the term ‘prescription’”); *United States v. Nazir*, 211 F. Supp. 2d 1372, 1375 (S.D. Fla. 2002) (“§ 353(b) does not define the word ‘prescription’”). Stelmachowski’s attempt to define “prescription” as a physician’s “written” or “oral prescription” is circular and inadequate.<sup>1</sup>

Where, as here, Congress does not define a term, a court should “apply its ordinary meaning.” *Barrett v. Illinois Dep’t of Corr.*, 803 F.3d 893, 896 (7th Cir. 2015); *accord Jackson v. Blitt & Gaines, P.C.*, 833 F.3d 860, 863 (7th Cir. 2016) (“The FDCPA does not define a ‘legal action,’ so we must determine its ordinary, contemporary, [and] common meaning at the time the provision was enacted”). Courts that have addressed the ordinary meaning of “prescription” have consistently held that it excludes fraudulent prescriptions.

In *Nazir*, for example, a physician was charged with misbranding by issuing “false prescriptions.” 211 F. Supp. 2d at 1373. The physician, with his codefendants, filed a motion to dismiss the indictment arguing that, although the physician had not examined the customers to

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<sup>1</sup> At most, Section 353(b)(1)’s references to “written” and “oral” prescriptions “of a practitioner licensed by law” identify acceptable forms of prescriptions—they do not define what a “prescription” is.

whom he issued prescriptions, he had “in fact issued prescriptions” and so “there can be no misbranding under the statute.” *Id.* at 1374. The court disagreed. Looking to dictionaries and medical treatises, the court concluded:

[P]rescription in § 353(b)(1), in common parlance, means only a bona fide order—i.e., directions for the preparation and administration of a medicine, remedy, or drug for a real patient who actually needs it after some sort of examination or consultation by a licensed doctor—and does not include pieces of paper by which physicians are directing the issuance of a medicine, remedy, or drug to patients who do not need it, persons they have never met, or individuals who do not exist.

*Id.* at 1375. Similarly, in *Smith*, the Fifth Circuit considered the appeal of a businessman convicted of misbranding for, among other things, employing a physician to issue thousands of prescriptions without examination. 573 F.3d at 643–45. The businessman argued that the district court erred in instructing the jury that “a prescription must be valid in order to preclude a charge of misbranding.” *Id.* at 646. The court, however, followed the reasoning in *Nazir* and prior precedent (*Brown v. United States*, 250 F.2d 745 (5th Cir. 1958)) to hold that only a “valid prescription” is exempt under Section 353(b)(1). *Id.* at 651–52; *see also id.* at 652–53 (further holding that the district court did not err in defining “valid prescription” as one issued in the “usual course of professional practice and for a legitimate medical purpose”).

Subsequent courts have echoed *Nazir* and *Smith*. The court in *United States v. Williams*, No. CR-10-216-HE, 2011 WL 4093884 (W.D. Okla. Sept. 14, 2011), for example, relied on *Nazir* and *Smith* in rejecting a motion to dismiss the misbranding count charged in an indictment. It held that that Section 353(b)(1) requires that covered drugs must be dispensed pursuant to a “valid prescription,” meaning, one resulting from a “bona fide physician-patient relationship.” *Williams*, 2011 WL 4093884, at \*4 (citing *Smith*, 573 F.3d at 650; *Nazir*, 211 F. Supp. 2d at 1375). To take another example, the court in *United States v. Lovin*, No. 07CR2016-IEG, 2009 WL 3634194, at \*8 (S.D. Cal. Oct. 30, 2009), adopted *Nazir* and *Smith*’s reasoning to reject

Stelmachowski's precise argument here—that Section 353(b)(1) has no validity “requirement.” See also *Riccio*, 43 F. Supp. 3d at 308 (S.D.N.Y. 2014) (relying on *Smith* in noting that a “prescription” is “issued in the usual course of professional practice and for a legitimate medical purpose, originating from a bona fide physician-patient relationship”). Indeed, even courts not specifically addressing the meaning of “prescription” under Section 353(b)(1) have read it to require a “valid prescription.” See *United States v. Inhenacho*, 716 F.3d 266, 270 (1st Cir. 2013) (“the act of dispensing a drug without a valid prescription” violates Section 353(b)(1)); *United States v. Munoz*, 430 F.3d 1357, 1366 (11th Cir. 2005) (“a prescription drug misbranded if it is dispensed other than pursuant to a valid prescription”); *Ouellette v. Mills*, 91 F. Supp. 3d 1, 5 (D. Me. 2015) (“any prescription drug dispensed without a valid prescription issued by a licensed practitioner” violates Section 353(b)(1)); *United States v. Oz*, No. 13-cr-00273, 2016 WL 1183041, at \*9 (D. Minn. Mar. 28, 2016) (“if a physician issues a prescription for a drug without a bona fide physician-patient relationship, he violates 21 U.S.C. §§ 331(a) and 353(b)(1)”); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 3:09-MD-02100-DRH, 2010 WL 4904478, at \*5 (S.D. Ill. Nov. 24, 2010) (prescription drugs “can only be legally distributed pursuant to a valid prescription from a licensed physician” under Section 353(b)(1) and certain state laws); see also *United States v. Travia*, 180 F. Supp. 2d 115, 117 (D.D.C. 2001) (Section 353(b)(1) “deems misbranded a prescription drug dispensed without a proper prescription”).

Defendant Stelmachowski provides no convincing rationale for departing from the reasoning in these cases. He cites one case from 1964 in support of his argument, *Dugan Drug Stores, Inc. v. United States*, 326 F.3d 835 (5th Cir. 1964), but it is of little relevance. In *Dugan Drugs*, a jury convicted a drug company of violating Section 353(b)(1) by refilling prescriptions

without physician authorization where the original prescriptions required refill authorization. 326 F.3d at 836–87. On appeal, the company contended that “the information [was] defective and the proof insufficient” because the original prescriptions were “not bona fide” in that they “were obtained by federal agents for the purpose of investigati[on].” *Id.* at 836. In other words, it did not argue that the conduct met Section 353(b)(1)’s exemption, rather, it argued that it was not subject to Section 353(b)(1) at all. *See id.* In rejecting that position, the Fifth Circuit held that an “unauthorized refill” of a covered drug violated Section 353(b)(1) regardless of the original prescription’s validity. *Id.* at 836–37. It did not decide, as *Smith* and *Nazir* did, whether a fraudulent prescription was protected under Section 353(b)(1).

**B. Although its consideration is unnecessary, legislative purpose confirms that the fraudulent prescriptions alleged in the Superseding Indictment are not “prescriptions” under the Act**

Courts “assume that the ordinary meaning of [statutory] language accurately expresses the legislative purpose.” *Our Country Home Enters., Inc. v. Comm’r of Internal Revenue*, 855 F.3d 773, 791 (7th Cir. 2017); *see also Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Lauer*, 49 F.3d 323, 326–27 (7th Cir. 1995) (courts “look beyond the express language of a statute only where such language is ambiguous, or where a literal interpretation would lead to absurd results or thwart the goals of the statutory scheme”). Because Section 353(b)(1)’s plain language compels the conclusion that the prescriptions alleged in the Superseding Indictment are not protected, the Court need not look to the Act’s legislative purpose.

Considering legislative purpose, however, only confirms as much. “The purpose of the misbranding laws is to protect the public from potentially dangerous drugs.” *Smith*, 573 F.3d at 652; *see also Kordel v. United States*, 335 U.S. 345, 349 (“The high purpose of the Act [is] to protect consumers who under present conditions are largely unable to protect themselves”);

*De Freese v. United States*, 270 F.2d 730, 735 (5th Cir. 1959) (the Act protects against “abuses in the sale of potent prescription drugs”). More specifically, through Section 353(b)(1), Congress enacted a prescription requirement for drugs that are “not safe for use except under the supervision of a practitioner.” 21 U.S.C. § 353(b)(1)(A) (emphasis added). Exempting the prescriptions alleged in the Superseding Indictment—those issued without a thorough examination, let alone supervision, and with fraudulent intent—would conflict with the purpose of having a prescription requirement. *See Nazir*, 211 F. Supp. 2d at 1376. Congress, moreover, intended the Act’s “coverage be as broad as its literal language indicates.” *United States v. Regenerative Scis., LLC*, 741 F.3d 1314, 1320 (D.C. Cir. 2014). Accordingly, applying the Act here comports not only with its plain language but also its legislative purpose. Stelmachowski’s arguments to the contrary are unsupported and unpersuasive. (R. 86 at 10; R. 99 at 3–4.)

**C. Because Section 353(b)(1) is not ambiguous, the rule of lenity does not apply**

Defendant Stelmachowski also argues that “to the extent the Court finds” Section 353(b)(1) “ambiguous,” the rule of lenity should apply. (R. 86 at 11.) The rule of lenity dictates that when a statute’s language is “grievous[ly]” ambiguous, the court should construe the statute in favor of the accused. *Chapman v. United States*, 500 U.S. 453, 462–63 (1991). For the reasons discussed above, the Court concludes that there is no ambiguity in the language of Section 353(b)(1). The rule of lenity, therefore, does not apply. *See United States v. Unthank*, 109 F.3d 1205, 1211 (7th Cir. 1997).

**II. Stelmachowski Was Not Prejudiced by the Government’s References to “Valid Prescriptions” Before the Grand Jury**

Stelmachowski next contends that the Court should dismiss Count One because the government erroneously instructed the grand jury on the law. Federal Rule of Criminal Procedure 12(b)(3) allows a defendant to seek a pretrial dismissal based on “an error in the

grand-jury proceedings.” Fed. R. Crim. P. 12(b)(3)(A)(v).

“Because the grand jury is an institution separate from the courts,” courts do not generally exercise “supervisory authority” over grand-jury proceedings. *United States v. Williams*, 504 U.S. 36, 47, 55 (1992); *see also United States v. Udziela*, 671 F.2d 995, 999 (7th Cir. 1982) (“Strictly speaking, the grand jury is a constitutional fixture in its own right, belonging to neither the executive nor the judicial branch . . . we must [therefore] take care not to encroach on legitimate executive activities before the grand jury.”). As a result, “courts may not dismiss an indictment for errors in grand jury proceedings unless such errors prejudiced the defendants.”<sup>2</sup> *United States v. Khan*, No. 15-CR-00286, 2017 WL 2362572, at \*17 (N.D. Ill. May 31, 2017) (quoting *Bank of Nova Scotia*, 487 U.S. at 254); *see also United States v. Vincent*, 416 F.3d 593, 600 (7th Cir. 2005). “Prejudice” occurs only “when the alleged violation had a substantial effect on the grand jury’s decision to indict or when it was quite doubtful that the decision to indict was free from that violation’s considerable influence.” *United States v. Brooks*, 125 F.3d 484, 497 (7th Cir. 1997); *see also Anderson*, 61 F.3d at 1296. A moving defendant bears the burden of showing such prejudice. *See, e.g., Boender*, 691 F. Supp. 2d at 843.

Defendant Stelmachowski has not met that burden. In his motion, he argues that when the agent testified before the grand jury that covered drugs could be dispensed only with a “valid prescription,” the government “erroneously narrowed the field of conduct exempted from the criminal provisions of the [Act].” (R. 86 at 14–16.) In his reply, he also argues that the

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<sup>2</sup> “Although prejudice need not be shown when ‘the structural protections of the grand jury have been so compromised as to render the proceedings fundamentally unfair,’” Stelmachowski “raises no such claim.” *United States v. Anderson*, 61 F.3d 1290, 1296 n. 4 (7th Cir. 1995) (quoting *Bank of Nova Scotia*, 487 U.S. 250, 257 (1988)). There is also no claim here of “systemic and pervasive prosecutorial misconduct before the grand jury that might allow a presumption of prejudice.” *Id.*

government narrowed the field further by quoting *Nazir*'s explanation of what constitutes a "valid prescription." (R. 99 at 4–5.) But as explained above, courts—this one included—read Section 353(b)(1) to require a "valid prescription," and *Nazir* is well-reasoned, often-cited law. See, e.g., *Smith*, 573 F.3d at 651–53; *Williams*, 2011 WL 4093884, at \*4; see also *Munoz*, 430 F.3d at 1366, 1376. The Court's review of the submitted grand-jury transcript excerpts supports that the government stated the prevailing law. (R. 86 at 14–15.) As such, Stelmachowski has failed to establish prejudice.

### **III. The Misbranding Statutes Are Not Unconstitutionally Vague**

Finally, Defendant Stelmachowski challenges the Misbranding Statutes as unconstitutionally vague. Again, Federal Rule of Criminal Procedure 12(b)(1) permits pretrial motions raising "any defense" that can be adjudicated without a trial. Fed. R. Crim. P. 12(b); see also *Boender*, 691 F. Supp. 2d at 837 (an indictment may be dismissed "if subject to a defense that raises a purely legal question").

"The Fifth Amendment's guarantee that '[n]o person shall . . . be deprived of life, liberty, or property, without due process of law' forbids vague criminal laws." *United States v. Coscia*, 866 F.3d 782, 791 (7th Cir. 2017) (quoting U.S. Const. amend. V). "This constitutional proscription gives rise to the general rule that 'prohibits the government from imposing sanctions under a criminal law so vague that it fails to give ordinary people fair notice of the conduct it punishes, or so standardless that it invites arbitrary enforcement.'" *Id.* (quoting *Welch v. United States*, --- U.S. ----, 136 S.Ct. 1257, 1262 (2016)); see also *United States v. Johnson*, 875 F.3d 360, 370 (7th Cir. 2017).

Stelmachowski makes only the first type of vagueness argument, that the law provides insufficient notice of what is proscribed. Such a "challenge to a statute's vagueness rest[s] on

the lack of notice, and hence may be overcome in any specific case where reasonable persons would know that their conduct is at risk.” *United States v. Lim*, 444 F.3d 910, 915 (7th Cir. 2006) (citing *Maynard v. Cartwright*, 486 U.S. 356, 361 (1988)). A statute “is not void for vagueness simply because it requires law enforcement to exercise some degree of judgment,” but “due process rejects ‘sweeping standard[s] [that] place[ ] unfettered discretion in the hands of police, judges, and juries to carry out arbitrary and erratic arrests and convictions.’” *Bell v. Keating*, 697 F.3d 445, 462–63 (7th Cir. 2012) (quoting *Wright v. New Jersey*, 469 U.S. 1146, 1151 (1985)). Put another way, a statute must not “set a net large enough to catch all possible offenders, and leave it to the courts to step inside and say who could be rightfully detained, and who should be set at large.” *Papachristou v. City of Jacksonville*, 405 U.S. 156, 165 (1972). Stelmachowski’s vagueness challenge is subject to an as-applied, rather than facial, analysis. *United States v. Morris*, 821 F.3d 877, 879 (7th Cir. 2016) (“Vagueness challenges to statutes that do not involve First Amendment interests are examined in light of the facts of the case at hand.”); (see also R. 99 at 2 (arguing that the Misbranding Statutes are “unconstitutionally vague as applied” to Stelmachowski)).

The Misbranding Statutes are not unconstitutionally vague as applied to the facts alleged against Stelmachowski in the Indictment. Setting aside unavailing protestations about the “awkward[ness]” of Count One, Stelmachowski makes two arguments in support of his challenge. First, he argues that Section 353(b)(1) does not put a “person of ordinary intelligence” on notice that “prescription” means “valid prescription.” (R. 86 at 17.) The Court disagrees. “Congress need not define every term, and a court may rely on the ordinary and natural meaning of words.” *United States v. Brown*, 637 F. App’x 935, 940 (7th Cir. 2016) (citing *United States v. Lanier*, 520 U.S. 259, 271 (1997), *Smith v. United States*, 508 U.S. 223,

228 (1993)). “Prescription,” as explained above, is ordinarily understood as a “valid prescription.” See *United States v. Cueto*, 151 F.3d 620, 636 (7th Cir. 1998) (holding that a statute was not unconstitutionally vague because the “plain and ordinary meaning” of the challenged phrase covered the defendant’s conduct). Accordingly, “a person of ordinary intelligence would understand that issuing an invalid prescription . . . or conspiring to do the same, constitutes misbranding.” *Oz*, 2016 WL 1183041, at \*9; see also *Travia*, 180 F. Supp. at 123 (“Congress has provided sufficient notice through [the Misbranding Statutes]; they are not so vague or standardless that the ordinary public is left uncertain as to what is prohibited”); *United States v. Girod*, No. CR 5:15-87-S-DCR, 2017 WL 760742, at \*1 (E.D. Ky. Feb. 27, 2017) (“courts have repeatedly upheld the constitutionality of the misbranding provisions of the FDCA in the face of vagueness challenges”).

Even assuming *arguendo* that a reasonable person would not understand that Section 353(b)(1) requires a “valid prescription” before dispensing covered drugs or causing them to be dispensed, the Court has “no difficulty concluding § 333(a)(2) provide[s] . . . ample warning” that it is “unlawful to do so with the intent to defraud or mislead,” as Stelmachowski is alleged to have done. *United States v. Hiland*, 909 F.2d 1114, 1127 (8th Cir. 1990); see also *Skilling v. United States*, 561 U.S. 358, 412 (2010) (a “*mens rea* requirement further blunts any notice concern); *Whatley v. Zatecky*, 833 F.3d 762, 780 (7th Cir. 2016) (“the Supreme Court has repeatedly held that imposing an intent requirement on an otherwise vague statute could save a law from a finding of impermissible vagueness”). Stelmachowski’s first vagueness argument thus fails.

Stelmachowski’s second argument is that the Misbranding Statutes are vague as applied because they do not expressly prohibit a person from “causing” covered drugs “to be dispensed”

without a prescription, as he is charged with doing. (R. 86 at 18.) The Court again disagrees. Count One charges Stelmachowski and Mikaitis with *conspiring* to “dispense” and to “cause to be dispensed” covered drugs in violation of the Misbranding Statutes. (R. 80 at 3.) Because the Misbranding Statutes provide adequate notice that covered drugs cannot be dispensed without a valid prescription, it follows that one cannot conspire with another to cause covered drugs to be dispensed without a valid prescription. No ordinary person would believe that facilitating the dispensing of fraudulent prescriptions—as Stelmachowski allegedly did by filling hundreds of Mikaitis’s prescriptions for tens of thousands of pills—is beyond the Misbranding Statutes’ reach. *Accord Lim*, 444 F.3d at 916 (“it is [not unfair] to require that one who deliberately goes perilously close to an area of proscribed conduct shall take risk that he may cross the line”) (quoting *Boyce Motor Lines v. United States*, 342 U.S 337, 340 (1952)). The Court therefore concludes that the Misbranding Statutes, as applied, are not unconstitutionally vague.<sup>3</sup>

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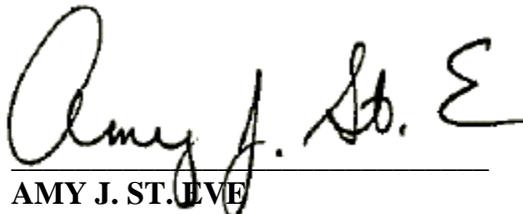
<sup>3</sup> In a footnote, Defendant Stelmachowski requests that, if Count One is not dismissed, the Court strike “all provisions of the indictment defining ‘prescription’ above and beyond the relevant statutory language as surplusage” under Federal Rule of Criminal Procedure 7(d). (R. 86 at 10, n. 1.) The Advisory Committee Notes to subdivision(d) explain that the “rule introduces a means of protecting the defendant against immaterial or irrelevant allegations in an indictment or information, which may, however, be prejudicial.” Fed. R. Crim. P. 7(d), Advisory Committee Note. A district court may strike “immaterial, irrelevant, or prejudicial” language from an indictment, *United States v. Marshall*, 985 F.2d 901, 905 (7th Cir.1993), “only if the targeted allegations are clearly not relevant to the charge and are inflammatory and prejudicial,” *United States v. Levine*, No. 05 CR 691, 2005 WL 3597707, at \*2 (N.D. Ill. Dec.29, 2005). The Court declines to strike the Superseding Indictment’s definitions of “prescription.” For the reasons outlined *supra*, those definitions generally accord with Act’s plain language and they therefore do not prejudice Stelmachowski.

**CONCLUSION**

For the foregoing reasons, the Court denies Defendant Stelmachowski's Motion to Dismiss Count One of the Superseding Indictment.

**Dated: February 12, 2018**

**ENTERED:**



A handwritten signature in black ink, appearing to read "Amy J. St. E", is written over a horizontal line.

**AMY J. ST. EVE**  
**United States District Court Judge**