UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA **v.** **TITILAYO AKINTOMIDE AKINYOYENU,** **Defendant.**	**Criminal Action No. 15-42 (JEB)**

MEMORANDUM OPINION

For many years, Defendant Titilayo Akinyoyenu, a pharmacist, ran a local drugstore in Washington, D.C. Following the turn of the century, he set up a website for his business, where he displayed and sold sundry medications. The Government criminally charged Defendant in 2015 because one of his products was Fioricet – a drug that contained butalbital and was therefore allegedly a controlled substance. The Indictment included, *inter alia*, two Controlled Substances Act offenses relating to the distribution of Fioricet without a valid prescription.

In advance of trial, Akinyoyenu now moves to dismiss both of these counts. They are legally insufficient, he says, because the Attorney General has issued a regulation that exempts Fioricet from a host of the CSA's requirements, including its provision that a prescription must precede distribution. As the Court agrees with Defendant that his CSA counts do not spell out crimes, it will grant his Motion to Dismiss.

I. Background

The Court gleans its understanding of the case by assuming as true the facts set forth in the Indictment. See United States v. Ballestas, 795 F.3d 138, 149 (D.C. Cir. 2015).

Akinyoyenu was a licensed pharmacist who owned and operated Apex Care Pharmacy here in Washington. See Indictment, Count One, ¶¶ 7-8. As the Internet age dawned, Defendant innovated. He hired a technology firm to design an online expansion to his brick-and-mortar business. Id., ¶ 17. The resulting websites – apexonlinepharmacy.com and bynextday.com – operated from January 2005 to June 2010 and offered for sale dozens of medications. Id., ¶¶ 12, 17-18.

Defendant's websites allowed visitors to place orders, but informed them that all orders would require a valid prescription up front. Id., ¶ 19. This was not entirely true; in fact, Akinyoyenu never asked for customers to provide prescriptions independently. Id., ¶¶ 18-20. Instead, customers simply filled out an online medical questionnaire when completing their orders; Defendant then forwarded those questionnaires to his own affiliated doctors – including Co-Defendant Alan Saltzman – who, for a fee, summarily approved the drug orders while issuing "prescriptions" for those drugs. Id. All in all, Akinyoyenu's online storefront grossed over $8 million in sales. Id., ¶ 22.

One of the drugs he sold was Fioricet – a combination drug containing acetaminophen, butalbital, and caffeine that is used to treat tension headaches. Id., Count One, Overt Acts, ¶¶ 3, 7-9, 13-14, 20; see Opp. at 3. In the Government's eyes, Defendant's online peddling of Fioricet without a valid prescription independently ran afoul of two federal drug statutes: the Federal Food, Drug, and Cosmetic Act and the Controlled Substances Act. First, under the FDCA, Fioricet requires a valid prescription because it is unsafe due to its toxicity or other possibly

deleterious effects. See 21 U.S.C. § 353(b)(1); see also Indictment, Count One, ¶¶ 2-3, 11-12. Second, under the CSA, because Fioricet contains butalbital (a derivative of barbituric acid), it allegedly is a Schedule III controlled substance and thereby requires a valid prescription. See 21 U.S.C. §§ 812(b)(3), 829(b), 829(e)(1); see also id. § 812(c), Schedule III(b)(1). The Government claims that Akinyoyenu's order-plus-questionnaire system, with its resulting rubberstamp prescriptions, violated these restrictions. See Indictment, Count One, ¶ 21.

Armed with these allegations, the Government indicted Akinyoyenu and Saltzman in March 2015. The first two counts in the Indictment listed CSA offenses under 21 U.S.C. §§ 841 and 846. In Count One, the Government charged the duo with conspiring to distribute a controlled substance by selling a product containing butalbital (Fioricet) "for other than a legitimate medical purpose and not in the usual course of professional practice" – that is, without a valid prescription. Id., ¶ 15. In Count Two, the Government charged them with conspiring to do the same through an online pharmacy, as prohibited by a recent amendment to the CSA that applies specifically to online pharmacies. Id., Count Two, ¶ 2. The Government also indicted the pair with conspiring both to dispense drugs without valid prescriptions in violation of the FDCA (Count Three) and to commit mail fraud (Count Four).

Akinyoyenu now moves to dismiss the two CSA counts on the ground that they fail to state criminal offenses.

II. Legal Standard

Before trial, a defendant may move to dismiss an indictment on the basis that it fails to state an offense – *i.e.*, that "the indictment does not charge a crime against the United States." United States v. Cotton, 535 U.S. 625, 631 (2002) (quoting Lamar v. United States, 240 U.S. 60, 65 (1916)); see Fed. R. Crim P. 12(b)(3)(B)(v) & 2014 advisory committee notes; Al Bahlul v.

United States, 767 F.3d 1, 10 n.6 (D.C. Cir. 2014) ("Failure to state an offense is simply another way of saying there is a defect in the indictment."); United States v. Hite, 950 F. Supp. 2d 23, 25-26 (D.D.C. 2013) ("Claims that a statute named in an indictment does not proscribe the alleged conduct are generally treated as claims that the indictment 'fails to state an offense.'") (quoting United States v. Teh, 535 F.3d 511, 515 (6th Cir. 2008)). The operative question is whether the allegations in the indictment, if proven, permit a jury to conclude that the defendant committed the criminal offense as charged. See United States v. Sanford, Ltd., 859 F. Supp. 2d 102, 107 (D.D.C. 2012); United States v. Bowdoin, 770 F. Supp. 2d 142, 146 (D.D.C. 2011).

In reviewing the indictment, the court affords deference to the "fundamental role of the grand jury." Ballestas, 795 F.3d at 148 (quoting Whitehouse v. U.S. Dist. Court, 53 F.3d 1349, 1360 (1st Cir. 1995)). As a result, "[a]dherence to the language of the indictment is essential because the Fifth Amendment requires that criminal prosecutions be limited to the unique allegations of the indictments returned by the grand jury." United States v. Hitt, 249 F.3d 1010, 1016 (D.C. Cir. 2001). The court accordingly cabins its analysis to "the face of the indictment and, more specifically, the language used to charge the crimes." United States v. Sunia, 643 F. Supp. 2d 51, 60 (D.D.C. 2009) (emphases omitted) (quoting United States v. Sharpe, 438 F.3d 1257, 1263 (11th Cir. 2006)).

III. Analysis

As is customary, the Court's analysis begins with the statute at hand. The CSA is a "comprehensive regime," designed "to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." Gonzales v. Raich, 545 U.S. 1, 12-13 (2005). Its individual Parts are the armatures that give it form: Part A lays out the Act's purpose; Part B defines controlled substances; Part C provides regulatory requirements for those substances (*e.g.*,

registering, labeling and packaging, recordkeeping); and then, when individuals spurn those requirements, Parts D and E provide criminal- and administrative-enforcement mechanisms, respectively. See 21 U.S.C. § 801 *et seq.* In broad brushstrokes, the Act thus makes it "unlawful to manufacture, distribute, dispense, or possess any controlled substance" unless an individual plays within the rules of the CSA's "closed regulatory system." Raich, 545 U.S. at 13.

This case hinges on the language of the separate yet similar statutory provisions in Part D that undergird Counts One and Two. Count One charges Akinyoyenu with conspiring to commit a ubiquitous federal drug offense under the Act, which reads:

> **(a) Unlawful acts**
>
> Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally –
>
> (1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance.

21 U.S.C. § 841(a) (emphasis added). Count Two charges Defendant with a largely equivalent conspiracy offense by means of the Internet, as prohibited by a 2008 amendment to the Act:

> **(h) Offenses involving dispensing of controlled substances by means of the Internet**
>
> **(1) In general**
>
> It shall be unlawful for any person to knowingly or intentionally –
>
> (A) deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized by this subchapter.

See Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. 110, § 3(f), 122 Stat. 4820, 4829 (2008) (codified as amended at 21 U.S.C. § 841(h)) (emphasis added). The alleged controlled substance in both counts is Fioricet. See Indictment, Count One, ¶ 15; id., Count Two, ¶ 2.

Akinyoyenu launches a two-pronged statutory attack on his Indictment. He argues first that Fioricet is not a "controlled substance" at all, but a medication outside the reach of the CSA. He next presses that, because Fioricet is exempt from the Act's prescription requirement, distributing that drug without a valid prescription is "authorized by this subchapter" – *i.e.*, by the CSA – and hence not criminal. 21 U.S.C. § 841(a)(1), (h)(1)(A). If for either reason Fioricet distribution is not "a crime against the United States," then Counts One and Two must be dismissed. Cotton, 535 U.S. at 631. The Court examines separately each challenge.

A. Controlled Substance

While some drugs are commonly thought of as controlled substances – *e.g.*, morphine or oxycodone – the status of Fioricet is less certain and depends on a telescoping series of statutory exceptions. Defendant seizes on these exceptions to argue that it is not a controlled substance.

As background, the CSA sets forth five Schedules of controlled substances (I through V, in decreasing severity) and lists as a Schedule III controlled substance "any material, compound, mixture, or preparation, which contains any quantity of . . . [a]ny substance which contains any quantity of a derivative of barbituric acid." Id. § 812(c), Schedule III(b)(1). The Government's syllogism goes thus: Butalbital is a derivative of barbituric acid, and Fioricet contains butalbital; *ergo*, Fioricet is a controlled substance. See Indictment, Count One, ¶¶ 2-3.

Not so fast. As Defendant points out, this classification of Fioricet holds up "[u]nless specifically excepted." 21 U.S.C. § 812(c), Schedule III(b)(1). Although neither party is particularly helpful in informing the Court as to how to locate the exceptions, the only sleuthing the Court need perform is to read the statute. Preceding the Schedules is an introductory section (followed by a colon) that provides that the Schedules list all controlled substances "unless and until amended pursuant to section 811 of this title." 21 U.S.C. § 812(c). The CSA, in this way,

contemplates that § 811 may provide for specific exceptions to the Schedules. Indeed it does. Three exceptions arguably could help Akinyoyenu. For one, that section permits the Attorney General to add or remove drugs from the Schedules through rulemaking and published regulations. Id. § 811(a)(2); see id. § 812(c) n.1. In this case, however, Akinyoyenu does not claim that she has done so for butalbital or Fioricet. See 21 C.F.R. § 1308.13(c)(3) (still listing "[a]ny substance which contains any quantity of a derivative of barbituric acid").

Section 811(g) also provides other, narrower exclusions and exemptions. See United States v. Emerson, 846 F.2d 541, 548 (9th Cir. 1988) ("[I]n 1984, Congress also amended section 811(g) to provide for the exemption of certain mixtures containing controlled substances."). As a second way out, if a non-narcotic drug may be lawfully sold without a prescription under the FDCA, the Attorney General is required to "exclude" it from the CSA as well. See 21 U.S.C. § 811(g)(1). Unfortunately for Defendant, the FDCA requires a prescription for Fioricet.

Third, the Attorney General may "exempt" prescription drugs containing controlled substances from any part of the CSA if she finds that the drug, by incorporating non-controlled substances, "vitiate[s] the potential for abuse" of the controlled substance. Id. § 811(g)(3)(A). Fioricet – this type of "combination" drug – finds temporary cover under this umbrella. This is because the Attorney General has issued a regulation exempting certain such combination drugs, see 21 C.F.R. § 1308.32, and published a list of those drugs, a list that includes Fioricet. See Mot., Exh. 2 (Exempt Prescription Products List) at 2. That regulation reads:

> The compounds, mixtures, or preparations that contain a nonnarcotic controlled substance . . . listed in the Table of Exempted Prescription Products have been exempted by the Administrator [of the Drug Enforcement Agency] from the application of [21 U.S.C. §§ 822-825, 827-829, 952-54] and [certain regulations] of this chapter for administrative purposes only. An exception to the above is that those products containing butalbital shall not be exempt from the requirement of 21 U.S.C.

> [§§] 952-954 concerning importation, exportation, transshipment and in-transit shipment of controlled substances.

21 C.F.R. § 1308.32. The regulation thus exempts Fioricet from some sections of the CSA, but, unfortunately for Akinyoyenu, not the one that classifies it as a controlled substance under Schedule III – namely, § 812(c).

Defendant nonetheless contends that under this regulation Fioricet is no longer a controlled substance as defined by the CSA. See generally 21 U.S.C. § 812(c) (introducing Schedules). In other words, he argues that, even without the regulation explicitly saying so, this exemption is a "specific except[ion]" that removes Fioricet from the rolls of Schedule III. It is difficult to see why this would be the case. The Attorney General had broad power to declassify Fioricet or drugs containing butalbital, but did not exercise that power. See id. § 811(a)(2). She instead issued a narrow regulation, which exempts Fioricet from only certain provisions of the Act, Schedule III not being one of them. See 21 C.F.R. § 1308.32. By necessary implication, the operative Schedules and the rest of the Act (which, lest it be forgotten, governs controlled substances) apply as normal and, left untouched, still treat Fioricet as a controlled substance. To put a nail in it, the exempting regulation Defendant relies on itself explicitly manifests concern about drugs containing butalbital: "[P]roducts containing butalbital shall not be exempt from the requirement[s] . . . concerning importation, exportation, transshipment and in-transit shipment of controlled substances." Id.

Summing up these statutes and regulations, then, Fioricet is free from many CSA requirements, but not all of them. It remains for the purposes of the Act a controlled substance, and this Court sides with the several other district courts that have reached this same result. See United States v. Oz, No. 13-273, 2016 WL 1183041, at *2 (D. Minn. Mar. 28, 2016) (rejecting argument "that Fioricet is not a 'controlled substance' under the CSA"); United States v. Riccio,

43 F. Supp. 3d 301, 304-06 (S.D.N.Y. 2014) (dismissing contention "that the regulatory exemption renders Fioricet a non-controlled substance for the purposes of the criminal statutes charged"); United States v. Williams, No. 10-216, 2010 WL 4669180, at *1 (W.D. Okla. Nov. 9, 2010) ("Fioricet remains a controlled substance despite being an exempted prescription product.").

B. Authorization

Defendant is not yet out of bullets. These exceptions, in fact, bleed into his second, more subtle argument about authorization under the CSA. Akinyoyenu contends that, even if Fioricet is a controlled substance, distributing it without a prescription is not criminal conduct; instead, such conduct is "authorized by this subchapter" – *viz.*, the CSA – because 21 C.F.R. § 1308.32 exempted the drug from the Act's prescription requirement. See 21 U.S.C. § 841(a)(1), (h)(1)(A).

To recap that central regulation: It exempts Fioricet "from the application of [21 U.S.C. §§ 822-825, 827-829, 952-54] . . . for administrative purposes only." 21 C.F.R. § 1308.32. One of those exempted sections – § 829 – is the CSA's prescription requirement. Akinyoyenu thus argues that he cannot be prosecuted because the exemption from § 829 constitutes an authorization to distribute Fioricet without a prescription.

The crux, here, is the interpretation of the statutory phrase "except as authorized by this subchapter." 21 U.S.C. § 841(a)(1), (h)(1)(A). Notably, the Government never quotes this clause; it only raises a regulatory counterargument centered on the clause "for administrative purposes only." 21 C.F.R. § 1308.32; see *infra* Section III.B.2. Focusing on the statute (as the Court must), if distributing controlled substances is illegal, except when authorized, three sequential questions arise: (1) What does it mean to be "authorized" by the CSA? (2) What

conduct is authorized as to Fioricet? and (3) Does the Indictment allege any unauthorized conduct on the part of Akinyoyenu? The Court tackles each in turn.

1. *Meaning of "Authorized"*

This phrase – "except as authorized by this subchapter" – pervades the CSA's criminal prohibitions in Part D. See, e.g., id. § 841(a)(1), (c)(1), (c)(2), (h)(1)(A), (h)(1)(B); § 842(a)(6), (a)(8); § 843(c)(2)(A); § 856(a). Except for rare and limited instances, however, this Part of the CSA describes what is prohibited but does not elucidate what is authorized. See id. § 841(h)(3) (providing limited exceptions for some online offenses). But the Act leaves a long trail of breadcrumbs. Part D is rife with sections that lay out actions that constitute criminal offenses unless they are authorized by the administrative requirements of Part C – for instance, the prerequisite that a practitioner register before she dispenses prescription drugs. See, e.g., id. § 841(h)(2)(C), (h)(3)(A)(i); § 842(a)(2), (a)(8), (b)(1); § 843(c)(2)(C)(i).

As illustrated by these cross-referencing exceptions, "except as authorized by this subchapter" means what its plain language suggests. Any section of the CSA, be it administrative or criminal in nature, can "authorize" conduct. If a person does what is so authorized, the CSA prevents her from being prosecuted criminally. See id. § 841(a)(1), (h)(1)(A). Through this interlocking scheme, Congress "devised 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, 545 U.S. at 13. "Each schedule is associated with a distinct set of controls regarding the manufacture, distribution, and use of the substances listed therein," and criminal prosecution provides the stick that keeps individuals from evading those controls. Id. at 14; see United States v. Vamos, 797 F.2d 1146, 1152 (2d Cir. 1986)

(discussing link between criminal provisions and regulatory controls, and noting §841 is "clearly directed at halting distribution outside the scope of a legitimate chain of possession.").

This relationship between the CSA's administrative scheme and its criminal prohibitions was illuminated by the Supreme Court in United States v. Moore, 423 U.S. 122 (1975). In Moore, a physician argued that he was registered under the administrative provisions of Part C of the Act – which expressly authorized registrants to handle controlled substances "to the extent authorized by their registration" – to distribute controlled substances and so could not be prosecuted under Part D. See 21 U.S.C. § 822(b).

The Supreme Court disagreed that mere registration provided blanket immunity from prosecution. Instead, Moore acknowledged that the registrants might be authorized but nonetheless analyzed their "scope of authorization," 423 U.S. at 140, and held that physicians could still be prosecuted if their acts fell "outside the usual course of professional practice." Id. at 124; see United States v. Limberopoulos, 26 F.3d 245, 249 (1st Cir. 1994). In other words, Part C's administrative requirements can and do authorize conduct; individuals' actions within the scope of that authorization are safe from prosecution, but extracurricular activities are not. See United States v. Hayes, 595 F.2d 258, 259 (5th Cir. 1979) ("The purpose of the regulation [implementing § 841(a)(1)] is to define the circumstances in which a physician or pharmacist who is registered to dispense controlled substances may nevertheless be held to have violated the proscription against manufacturing, distributing or dispensing a controlled substance . . . ."); Estate of Klieman v. Palestinian Auth., 424 F. Supp. 2d 153, 164-65 (D.D.C. 2006) ("In other words, a physician or pharmacist is immune from criminal prosecution only when acting as a doctor or druggist 'in the course of professional practice,' not when he or she 'step[s] outside the bounds of professional practice' . . . .") (quoting Moore, 423 U.S. at 132); see also 3 Leonard B.

Sand, Modern Federal Jury Instructions – Criminal ¶ 56-18 comment (2016) (explaining that "[a]n order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. § 829)," and a practitioner filling or issuing such a prescription would "be subject to the penalties provided for violations of the provisions of law relating to controlled substances") (quoting 21 C.F.R. § 1306.04(a)).

The point, then, is to analyze the scope of authorization in the CSA as a whole for any given controlled substance, leading to the next inquiry: What conduct is authorized with respect to Fioricet?

2. *Scope of Authorization for Fioricet*

The scope of CSA authorizations for Fioricet is more convoluted than for the usual case, and preceding sections of this Opinion have previewed some of that complexity. See *supra* Section III.A. There is, however, an added intricacy. Unlike the run-of-the-mill prescription-drug cases – *e.g.*, Moore, 423 U.S. 122 – where § 822 (the registration requirement) is used to determine the scope of authorized activities for the controlled substance, the regulation here also exempts Fioricet from § 822. See 21 C.F.R. § 1308.32. This leaves what is authorized as to Fioricet an open question.

Akinyoyenu answers by arguing that the regulatory exemption (21 C.F.R. § 1308.32) from the prescription requirement (21 U.S.C. § 829) promulgated pursuant to the Attorney General's statutory power (21 U.S.C. § 811(g)(3)(A)) functions as authorization under the CSA to distribute Fioricet without a prescription. The Government does not even discuss the substance of the prescription requirement, apparently recycling its brief from another case in which the authorization issue was not raised. See Oz, No. 13-273, ECF No. 400. This plug-and-

play legal analysis is not a winning formula, as the Court agrees with Defendant that the CSA does indeed authorize distribution of Fioricet without a prescription.

The Court first explores generally how an exemption can itself be an authorization. Ordinary speech guides the analysis. A missive – "You may eat" – is a clear formulation of an authorization. The word "authorization," however, is capacious enough to capture also exemptions from prohibitions – for instance, "You need not stop yourself from eating." In lay terms, such exemptions are merely a roundabout, double-negative way of authorizing conduct (in this digestible example, eating). Indeed, courts have recognized that the term "authorized" is broad. It runs "the entire gamut from mere acquiescence to the kind of approval which endows the person authorized with some of the powers of the authorizing authority." Rhodes v. United States, 760 F.2d 1180, 1185 (11th Cir. 1985) (emphasis added); see also Stop & Shop Cos. v. Fed. Ins. Co., 136 F.3d 71, 74 (1st Cir. 1998) (surveying range of definitions of "authorized"); Authorize, Black's Law Dictionary (10th ed. 2014) (listing, as one definition, "to sanction").

A recent Ninth Circuit opinion is particularly instructive as to this broad definition. There, the court considered whether certain unlawfully present aliens – *i.e.*, aliens prohibited from being in the United States – were nonetheless "authorized" to be in the country for the purpose of obtaining a state driver's license. See Ariz. Dream Act Coalition v. Brewer, 818 F.3d 901 (9th Cir. 2016). The Ninth Circuit held they were "authorized" because they were beneficiaries of the Deferred Action for Childhood Arrivals (DACA) program, which temporarily exempted those aliens from deportation. Id. at 915-17. That is, even though no statute expressly designated those aliens as "lawfully admitted," DACA for the time being halted enforcement of immigration prohibitions, and so those individuals could fairly be considered to be "'authorized'" to be here. Id. at 916 (quoting 8 U.S.C. § 1182(a)(9)(B)(ii)).

Turning back to this case, nothing in the CSA expressly tells individuals that they can distribute Fioricet without a prescription. But a rule issued pursuant to the Act, see 21 C.F.R. § 1308.32, exempts Fioricet from the prohibition against distribution without a valid prescription that is implicated in Count One. See 21 U.S.C. § 829(b). Fioricet is likewise exempted from the online-distribution prescription requirement that is implicated in Count Two. See id. § 829(e)(1). Because individuals are exempt from these prohibitions against distributing Fioricet without a prescription, the Court can fairly say that they are "authorized by th[e] [CSA]" to do so. Id. § 841(a)(1), (h)(1)(A).

The Government's counterpoint focuses not on the meaning of authorization under the CSA but on the words "for administrative purposes only," which appear at the end of § 1308.32's exempting language. It argues that the regulation, by incorporating this phrase, definitively "only ha[s] an administrative, as opposed to criminal, purpose." Opp. at 10. To put it differently, the Government's position is that prescription-less distribution is administratively, not criminally, authorized conduct – and, by extension, though administrative enforcement might be halted, criminal enforcement marches onward. See id. at 11-12; see also Oz, 2016 WL 1183041, at *4 ("Administrative enforcement of the CSA is distinct from its criminal enforcement."); Riccio, 43 F. Supp. 3d at 305-06 ("[A]dministrative enforcement for violations of the Controlled Substantive [*sic*] Act is entirely separate and distinct from criminal prosecutions like this one.").

This argument's initially attractive facade quickly crumbles. To begin, it makes little sense to immunize physicians and pharmacists from administrative, but not criminal, enforcement. Administrative penalties are commonly thought of as a less severe form of punishment than criminal penalties. So, relieving individuals from the brunt of administrative-law lashes only to subject them to the criminal-law firing squad would be a mindless endeavor.

Cf. Mourning v. Family Pubs. Serv., Inc., 411 U.S. 356, 376 (1973) ("In light of the emphasis Congress placed on agency rule making and on private and administrative enforcement of the Act, we cannot conclude that Congress intended those who failed to comply with regulations to be subject to no penalty or to criminal penalties alone."). In other words, if the Government's reading were correct, no doctor in her right mind would exercise her power under § 1308.32 to distribute Fioricet without a valid prescription; though she might escape administrative penalties, the threat of criminal sanctions would loom large. The Government, with its laser-like focus on the words "for administrative purposes only," makes the whole of § 1308.32 gratuitous. The Court refuses to read the CSA's regulations in such a fashion. See Sec'y of Labor v. Twentymile Coal Co., 411 F.3d 256, 261 (D.C. Cir. 2005) ("This Court will not adopt an interpretation of a statute or regulation when such an interpretation would render the particular law meaningless.").

Then what does "for administrative purposes only" mean? Interpreting those few words demands some powerful divination. "[F]or administrative purposes only," on its face, appears akin to those banal bureaucratic margin-fillers – *e.g.*, "for internal use only" or "for administrative use only." When seen in an office setting, it might signal that the document being filled out is indeed merely a form destined to vanish into stacks of paperwork. When seen in a federal regulation, it comes across as less familiar and its meaning is less certain. See Riccio, 43 F. Supp. 3d at 305 (acknowledging elusiveness of "the precise connotation and ambit of the exemption 'for administrative purposes only'").

Focusing on this uncertainty, Defendant presents a Drug Enforcement Administration internal memorandum that acknowledges, "[T]his exemption is likely to cause some confusion." Mot., Exh. 28 (DEA Memorandum) at 4. Akinyoyenu further digs through decades of regulatory history to argue that the words are instead a now-obsolete holdover from an era when the

regulation's original 1971 language gave only an interim list of exempted drugs. At that time, the regulation read:

> (a) Until criteria are adopted by the Bureau [of Narcotics and Dangerous Drugs] by which the Director may determine whether to except any compound mixture, or preparation containing any depressant or stimulant substance . . . from the application of all or any part of the Act pursuant to [21 U.S.C. § 812], the drugs set forth in paragraph (b) of this section have been excepted by the Director from application of [21 U.S.C. §§ 825, 827-29, 952-54] for administrative purposes only.

36 Fed. Reg. 7,776, 7,805 (Apr. 24, 1971) (emphases added) (quoting predecessor to 21 C.F.R. § 1308.32). Paragraph (b) then gave a list of exempted drugs that was temporary and, hence, "for administrative purposes only." See id. at 7,806-11.

Defendant's theory – again, unimpeached by the Government – is that once criteria for exemptions were developed, regulators forgot about this forgettable phrase. They apparently did not realize their negligence for a decade. In 1981, DEA finally noted in its regulatory agenda that though § 1308.32 "indicates that no such criteria [for exempt prescription products] have yet been adopted by the Administrator[,] [i]n fact, . . . DEA has been using criteria previously established in 1967 . . . and shall continue to do so." 46 Fed. Reg. 10,105, 10,105 (Jan. 30, 1981) (emphasis added). Spring cleaning started two years later, when the Agency removed paragraph (b)'s interim list, while keeping its adverbial prepositional phrase "for administrative purposes only." See 48 Fed. Reg. 10,644, 10,645 (Mar. 14, 1983). DEA at last took its eraser to "[u]ntil criteria are adopted by the Bureau" in 1987, but the other troublesome modifier was again neglected. See 52 Fed. Reg. 9,802 9,803 (Mar. 27, 1987). Without its bookend, however, "for administrative purpose only" appears more unmoored from the original purpose of § 1308.32.

Recounting this history, Akinyoyenu at least offers an interpretation that is rational: Once meant to signal temporariness, "for administrative purposes only" is now an accidental holdover.

Other regulations likewise suggest that the phrase is inserted only to signal a lack of finality. See, e.g., 14 C.F.R § 302.20(d) (designating that permission to intervene in hearing was "for administrative purposes only" and did not signify intervenor's substantial interest); 43 C.F.R. § 3106.7-1 (providing that approvals of land transfers were "for administrative purposes only" and did not certify title), § 3135.1-1(f) (same); 40 C.F.R. § 35.2050 (noting that EPA approval of facility plans was "for administrative purposes only" and did not relieve grantee of responsibilities); 47 C.F.R. § 1.1405 (assigning file number to complaints "for administrative purposes only" without certifying procedural compliance). Yet with drug criteria finalized for almost fifty years, "for administrative purposes only" might now very well mean nothing at all.

The Government rejoins that this interpretation renders these words "wholly superfluous." Opp. at 11. Fair enough. But this nonetheless places the Court in a regulatory-interpretation Catch-22. Either it sides with the Government to render the regulation practically ineffective, or it sides with Defendant to render the banal (and perhaps meaningless) phrase "for administrative purposes only" surplusage. The sacrifice is easy – a few words saves the whole. A drafter, moreover, could easily avoid this problem and preserve criminal enforcement. For an example, the Court need look no further than a neighboring rule, which likewise exempts certain controlled substances (chemical preparations used for education or research). That section includes a subsection – "Criminal penalties" – that quite definitively states, "No exemption . . . affects the criminal liability for illegal manufacture, distribution, or possession of controlled substances contained in the exempt chemical preparation." 21 C.F.R. § 1308.24(f). Without similarly clear language in § 1308.32, however, the Court rejects the Government's Panglossian view that the regulation is somehow perfect as is and instead adopts Akinyoyenu's more sensible approach.

In rejecting the Government's proposed administrative–criminal distinction, the Court also looks to the broader structure of the Act. Though administrative and criminal enforcement are technically independent proceedings, see 21 U.S.C. § 847; 21 C.F.R. § 1301.41(b), they are nonetheless complementary. Part E of the CSA explicitly permits the DEA to institute administrative-enforcement proceedings before a violation is referred for prosecution under Part D. See 21 U.S.C. § 883. In those cases, DEA's notice to a physician or pharmacist is a warning shot that can induce compliance. See Kenneth Baumgartner, Controlled Substances Handbook § 1316 (2015) ("Frequently it represents a last ditch effort by DEA to achieve compliance voluntarily, that is, before the case is referred for prosecution."). And when compliance eludes DEA, administrative proceedings maintain an added criminal function: "DEA may also use the proceedings as a means of formal notice of violations, thereby establishing the element of intent necessary to develop a criminal case if the violations continue." Id.

Understanding this relationship makes the Government's interpretation all the more confusing. The Government itself would seemingly lose much by discarding administrative enforcement while hanging on to only criminal enforcement. Doing so would both waste prosecutorial resources on cases that could be easily resolved through voluntary compliance and also neuter those same prosecutions by doing away with valuable investigative powers. See, e.g., 21 U.S.C. § 876 (subpoenas), § 879 (search warrants), § 880 (administrative inspections and warrants). The Government's reading is even more suspect in the context of Fioricet. That drug is apparently less harmful than other Schedule III drugs, given its lack of potential for abuse, see 21 U.S.C. § 811(g)(3)(A); one would think that the Government would thus particularly favor regulatory compliance measures instead of upping the ante to leave only criminal prosecution as an option. See Mourning, 411 U.S. at 376.

Subscribing to the Government's theory that the administrative and criminal parts (Parts D and E) are divorced from one another thus requires the Court to cross its eyes and see two Acts in the place of one. The CSA's Parts, however, have always been intertwined. See Raich, 545 U.S. at 13 (describing Act as a cohesive "closed regulatory system"). Whether conduct is authorized under Part C informs whether it is subject to both criminal (Part D) and administrative (Part E) enforcement under the Act. See Moore, 423 U.S. at 140 (explaining Part C's registration section can "define[] the scope of authorization under the Act" for Part D's criminal prosecutions); see also 21 U.S.C. § 883 (permitting administrative enforcement of conduct prior to criminal enforcement). The statute's language is appropriately simple: Either conduct is authorized or it is not. See 21 U.S.C. § 841(a)(1), (h)(1)(A). To use an everyday example, it would likewise be farfetched to argue that a child's parents had not authorized her to take a cookie from the cookie jar when she had the say-so of her father while her mother was not home. The point is her parents allowed her to snack. Here, the point is that the CSA allows Fioricet to be distributed without a prescription, for whatever reason, administrative or otherwise.

Beyond all the above reasons that caution against the Government's stance, the Court can additionally draw support from the rule of lenity, an interpretive rule that "requires ambiguous criminal laws to be interpreted in favor of the defendants subjected to them." United States v. Santos, 553 U.S. 507, 514 (2008). The Court invokes the rule of lenity, of course, only after it has in preceding discussions "consider[ed] [the Act's] text, structure, history, and purpose." Barber v. Thomas, 560 U.S. 474, 488 (2010). At a minimum, the word "authorized" has multiple meanings, see Rhodes, 760 F.2d at 1185-86; Stop & Shop, 136 F.3d at 74, and Congress has "not clearly prescribed" that the term is peculiarly dependent on some administrative–criminal-authorization distinction in the context of the CSA. Santos, 553 U.S. at 514. Without any

evidence why "authorized" should be construed narrowly – and indeed, with much evidence that its natural reading is a broad one – to hold that this distinction matters would be to "guess" that Congress somehow implied it into the CSA. Barber, 560 U.S. at 488.

Even if the distinction somehow mattered, moreover, the rule of lenity is still particularly appropriate given the difficulty an ordinary pharmacist would have in discerning § 1308.32's meaning. See United States v. Bass, 404 U.S. 336, 348 (1971) (highlighting principle that "a fair warning should be given to the world in language that the common world will understand, of what the law intends to do if a certain line is passed") (quoting McBoyle v. United States, 283 U.S. 25, 27 (1931)). As is evident by the lengths Akinyoyenu's counsel have gone to unearth their version of the regulation's scope, the ensuing implication that an ordinary pharmacist could engage in such a deep regulatory analysis makes the Government's administrative-purpose argument flawed at best and untenable at worst. The Court declines to force ordinary persons to speculate as to some hidden duality in the word "authorized" and then to playact administrative lawyers. It instead sticks with its interpretation that individuals are authorized under the CSA to distribute Fioricet without a prescription.

3. *Allegations in Indictment*

The Court last examines the Indictment's specific language to determine whether it alleges only authorized conduct outside the bounds of criminal enforcement. See Hitt, 249 F.3d at 1016. It is clear that Counts One and Two focus on Defendant's distribution of Fioricet without a valid prescription. Count One charges Akinyoyenu with conspiring "to distribute and cause to be distributed a Schedule III controlled substance, butalbital (also marketed as Fioricet), for other than a legitimate medical purpose and not in the usual course of professional practice." Indictment, Count One, ¶ 15. Namely, Defendant caused "controlled substances . . . to be

distributed through orders purporting to be prescriptions which in fact, were **not** issued for a legitimate medical purpose by individual practitioners acting in the usual course of professional practice." Id., ¶ 21; see id. ("Consequently the 'prescriptions' issued for the customers of Apex website were invalid because they were **not** issued for a legitimate medical purpose by individual practitioners acting in the usual course of professional practice."). Count Two charges Akinyoyenu with doing the same, except specifically online this time, "by offering to fill prescriptions for a controlled substance based solely on customers completing online medical questionnaires." Id., Count Two, ¶ 2. Both counts, therefore, explicitly ground themselves in the prescription requirements found in the exempted § 829. See id., Count One, ¶ 2; id., Count Two, ¶ 2. As Counts One and Two rely on the invalidity of Fioricet prescriptions, they fail to state offenses.

Such a ruling, however, presents a conflict, according to the Government: Three other district courts have supposedly permitted similar Fioricet prosecutions to go forward despite motions to dismiss, see Oz, 2016 WL 1183041; Riccio, 43 F. Supp. 3d 301; Williams, 2010 WL 4669180, and still other defendants have pleaded guilty. Three non-circuit cases (and a few guilty pleas, which are not substantive law) is no long line of precedent; indeed, Fioricet prosecutions appear to be a recent phenomenon. See DEA Memorandum (developing, in 2010, "The Argument for Prosecutions Related to Fioricet"). Plus, each of these cases is easily distinguishable.

First, in Williams the court rejected defendant's argument that "Fioricet is not a controlled substance." 2010 WL 4669180, at *1; see also Opp., Exh. 1 (United States v. Garwood, No. 10-216 (W.D. Okla. Oct. 6, 2010)) (earlier order by same judge). This Court, of course, agrees with that conclusion. See *supra* Section III.A. For the same reason, Riccio –

which dealt with whether "the regulatory exemption renders Fioricet a non-controlled substance for the purposes of the criminal statutes charged in the Indictment" – is also inapposite. See 43 F. Supp. 3d at 304-05. Far from being definitive contravening authorities, then, the holdings in Williams and Riccio are endorsed by this Court.

The third and final case considered the more comparable issue of whether § 1308.32 "exempt[s] [Fioricet] from the criminal provisions of the CSA" and held that it did not. Oz, 2016 WL 1183041, at *6. The Court, fundamentally, agrees with Oz's holding that Fioricet is not exempt *in toto*. Indeed, the whole point is that the criminal provisions do apply, but that those very provisions each expressly incorporate an authorization exception, leading courts then to examine the scope of authorization for the controlled substance. Oz cannot be said to be contrary authority because it did not analyze authorization vis-à-vis Fioricet's exemption from the prescription requirement. See id. at *2-6, *9 n.13. The facts of Oz, moreover, demonstrate how this distinction can make or break an indictment. That indictment additionally alleged that the defendants violated 21 U.S.C. § 831, which requires certain information to be posted on an online pharmacy's website. See Oz, No. 13-273, ECF No. 5 (Oz Indictment) at 39. Because the relevant regulation does not exempt Fioricet from § 831's online requirements, see 21 C.F.R. § 1308.32, the defendants in Oz who flouted § 831 were not engaging in conduct authorized under the CSA. In fact, the Oz court explicitly relied on this nuance – namely, that § 831 is "not included in the list of statutory sections from which Fioricet is exempted for administrative purposes." 2016 WL 1183041, at *4. Nothing in this Opinion suggests that had Akinyoyenu's Indictment contained those allegations it would have been dismissed.

The Court, therefore, concludes that, as the CSA authorizes individuals to distribute Fioricet without a prescription and Counts One and Two rely on a contrary conclusion, prosecution for these authorized activities cannot go forward. Those counts will be dismissed.

IV. Conclusion

For the reasons set forth above, the Court will grant Defendant's Motion in a separate Order to be issued this day.

/s/ *James E. Boasberg*
JAMES E. BOASBERG
United States District Judge

Date: August 4, 2016