

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF
KENTUCKY

United States v. Michael

260 F. Supp. 3d 845 (W.D. Ky. 2017) · Decided May 15, 2017

SUMMARY

The court denied defendants Philip E. Michael II and Meds 2 Go Express Pharmacy, Inc.’s motion to dismiss Count 1 of a second superseding indictment charging conspiracy to unlawfully distribute and dispense controlled substances over the Internet. The court held that the indictment sufficiently alleged the time, means, objects, and knowing participation required for a conspiracy charge. It further held that Fioricet, containing the Schedule III controlled substance butalbital, remained subject to the prescription requirement for purposes of criminal prosecution notwithstanding an administrative exemption in 21 C.F.R. § 1308.32.

CASE DETAILS

COURT	United States District Court for the Western District of Kentucky
WRITING FOR THE COURT	Charles R. Simpson III, Senior District Judge
JURISDICTION	Kentucky
DECIDED	May 15, 2017
DISPOSITION	other
PROCEDURAL POSTURE	Defendants moved to dismiss Count 1 of the Second Superseding Indictment for insufficiency of the indictment and on the ground that Fioricet was exempt from the Controlled Substances Act's prescription requirements.
STANDARD OF REVIEW	On a motion to dismiss an indictment, the court construes the indictment as a whole, accepts its factual allegations as true, and determines whether it contains the elements of the offense and sufficiently apprises the defendants of the accusation. The government need not prove its case in response to a motion to dismiss.
PRECEDENTIAL VALUE	Published federal district court memorandum opinion; persuasive authority within the district and nonbinding authority elsewhere.
PARTIES	Philip E. Michael, II, Meds 2 Go Express Pharmacy, Inc. v. United States

TOPICS

criminal procedure

conspiracy

statutory interpretation

rule of lenity

health law

PRACTICE AREAS

criminal law

criminal procedure

controlled substances

health law

statutory interpretation

QUESTIONS PRESENTED

1. Whether Count 1 of the Second Superseding Indictment sufficiently alleged the essential facts of a conspiracy to unlawfully distribute and dispense controlled substances.
2. Whether Fioricet remained a controlled substance notwithstanding 21 C.F.R. § 1308.32.
3. Whether 21 C.F.R. § 1308.32 authorized dispensing Fioricet without a valid prescription for purposes of criminal prosecution under 21 U.S.C. § 841(h)(1).
4. Whether the rule of lenity required dismissal because of alleged uncertainty concerning the effect of the exemption regulation.

HOLDINGS

1. Count 1 sufficiently charged a conspiracy to unlawfully distribute and dispense controlled substances because it alleged the time period, location, means, objects, participants, and unlawful conduct comprising the alleged agreement.
2. Fioricet remained a Schedule III controlled substance because it contained butalbital, a derivative of barbituric acid listed in Schedule III.
3. The exemption in 21 C.F.R. § 1308.32 did not authorize the distribution or dispensing of Fioricet without a valid prescription or through an unregistered online pharmacy for purposes of criminal charges under 21 U.S.C. § 841(h)(1).
4. The rule of lenity did not require dismissal of Count 1 because the statutory and regulatory language did not create the type of grievous ambiguity necessary to invoke lenity.

KEY QUOTATIONS

“What is required of the indictment, however, is merely a recitation of facts sufficient to inform the defendants of the crime with which they are charged.” (849)

“The Exempting Regulation does not authorize the distribution of Fioricet without a valid prescription or through an online pharmacy that lacks DEA registration for the purposes of criminal charges under 21 U.S.C. § 841(h)(1).” (854)

FACTUAL BACKGROUND

The Second Superseding Indictment alleged that, from approximately October 2010 through April 2012, Michael, Euton Laing, Meds 2 Go, and others participated in an Internet-based scheme to sell, distribute, and dispense prescription drugs without valid prescriptions. The alleged scheme involved online medical

questionnaires, purported physician consultations that did not occur, prescriptions issued without meaningful patient contact, and fulfillment by pharmacies including Meds 2 Go. Count 1 identified Fioricet, containing butalbital, as a Schedule III controlled substance and alleged that the defendants distributed it through the Internet without valid prescriptions.

PROCEDURAL HISTORY

The United States charged Philip E. Michael II, Meds 2 Go Express Pharmacy, Inc., and others in a conspiracy involving the online distribution and dispensing of controlled substances without valid prescriptions. Michael and Meds 2 Go moved to dismiss Count 1. The district court denied the motion, concluding that the indictment sufficiently described the charged conspiracy and that the applicable exemption regulation did not authorize dispensing Fioricet without a valid prescription.

DISPOSITION

other

CASES CITED

- Hamling v. United States, 418 U.S. 87, 177 (1974)
- Russell v. United States, 369 U.S. 749, 761, 767 (1962)
- United States v. Hess, 124 U.S. 483, 487 (1888)
- United States v. Debrow, 346 U.S. 374, 376 (1953)
- Evans v. United States, 153 U.S. 584, 587-88 (1894)
- Batchelor v. United States, 156 U.S. 426 (1895)
- Cochran v. United States, 157 U.S. 286, 290 (1895)
- United States v. Reed, 77 F.3d 139, 140 n.1 (6th Cir. 1996) (en banc)
- United States v. Davis, 306 F.3d 398, 411 (6th Cir. 2002)
- United States v. Ihenacho, 716 F.3d 266, 277 (1st Cir. 2013)
- United States v. Bhutani, 266 F.3d 661, 670 (7th Cir. 2001)
- United States v. Pearce, 912 F.2d 159, 161-62 (6th Cir. 1990)
- United States v. Blakeney, 942 F.2d 1001, 1009-10 (6th Cir. 1991)
- United States v. Ellzey, 874 F.2d 324, 328 (6th Cir. 1989)
- United States v. Bavers, 787 F.2d 1022, 1026 (6th Cir. 1985)
- United States v. Hughes, 891 F.2d 597, 601 (6th Cir. 1989)
- United States v. Oz, 2017 WL 342069 (D. Minn. Jan. 23, 2017)
- United States v. Oz, 2016 WL 1183041 (D. Minn. Mar. 28, 2016)
- United States v. Akinyoyenu, 199 F. Supp. 3d 106, 109-18 (D.D.C. 2016)
- United States v. Riccio, 43 F. Supp. 3d 301, 304-06 (S.D.N.Y. 2014)
- Lamie v. United States Trustee, 540 U.S. 526, 534 (2004)
- Contemporary Industries Corp. v. Frost, 564 F.3d 981, 985 (8th Cir. 2009)

- United States v. Smith, 573 F.3d 639, 650-53 (8th Cir. 2009)

OPINION

III, J.

MEMORANDUM OPINION Charles R. Simpson III, Senior Judge This matter is before the court on motion of the defendants, Philip E. Michael, II (“Michael”) and Meds 2 Go Express Pharmacy, Inc. (“Meds 2 Go”), to dismiss Count 1 of the Second Superseding Indictment (“SSI”) charging them with knowingly and intentionally conspiring to unlawfully distribute and dispense controlled substances.^{1,2} The defendants have moved to dismiss these counts for insufficiency of the indictment, citing *Hamling v. United States*, 418 U.S. 87, 177, 94 S.Ct.

2887, 41 L.Ed.2d 590 (1974) and *Russell v. United States*, 369 U.S. 749, 761, 82 S.Ct. 1038, 8 L.Ed.2d 240 (1962). An indictment must provide a “plain, concise, and definite written statement of the essential facts constituting the offense charged.” Fed.R.Crim.P. 7(c).

The purpose of an indictment is “to inform the defendant of the nature of the accusation against him.” *Russell*, 369 U.S. at 767, 82 S.Ct. 1038 (quoting *United States v. Hess*, 124 U.S. 483, 487, 8 S.Ct. 571, 31 L.Ed. 516 (1888)). “The Federal Rules of Criminal Procedure, 18 U.S.C.A., were designed to eliminate technicalities in criminal pleading and are to be construed to secure simplicity in procedure.

Rule 2, F.R.Crim.Proc.” *United States v. Debrow*, 346 U.S. 374, 376, 74 S.Ct. 113, 98 L.Ed. 92 (1953). As explained by the Supreme Court as early as 1895, an indictment need not be a literary work of art: [T]he true test is, not whether it might possibly have been made more certain, but whether it contains every element of the offense intended to be charged, and sufficiently apprises the defendant of what he must be prepared to meet, and, in case any other proceedings are taken against him for a similar offense, whether the record shows with accuracy to what extent he may plead a former acquittal or conviction.

Evans v. U.S., 153 U.S. 584, 587, 588, 14 S.Ct. 934 [38 L.Ed. 830 (1894)]; *Batchelor v. U.S.*, 156 U.S. 426, 15 S.Ct. 446 [39 L.Ed. 478 (1895)]. *Cochran v. United States*, 157 U.S. 286, 290, 15 S.Ct. 628, 630, 39 L.Ed. 704 (1895).

The indictment must be read as a whole, accepting the factual allegations as true, and construing those allegations in a practical sense with all the necessary implications. *United States v. Reed*, 77 F.3d 139, 140 n. 1 (6th Cir. 1996) (en banc). An indictment is to be construed liberally in favor of its sufficiency. *United States v. Davis*, 306 F.3d 398, 411 (6th Cir.

2002). Count 1 of the SSI alleges that From at least in or about October 2010 and continuing until at least in or about April 2012, in the Western District of Kentucky, Jefferson County, Kentucky, and elsewhere, PHILIP MICHAEL, EUTON LAING, defendants herein, combined, conspired,

confederated, and agreed with one another and others, known and unknown to the Grand Jury, to engage in a scheme to sell distribute, and dispense prescription drugs over the Internet, and to deliver those prescription drugs to customers, without issuance of valid prescriptions.

SSI, ¶ 23. The paragraph then goes on to describe in detail the means by which online drug orders were fulfilled without the issuance of a valid prescription. SSI, ¶ 23(a)-(k). The SSI specifically alleges that Michael billed the website operators for prescriptions which Aracoma and Meds 2 Go pharmacies filled, and funds in payment were wired to Michael's accounts.

SSI, ¶¶ 24-27. Additionally, the SSI alleges that Laing and others were paid by the website operators for transmission of (invalid)³ prescriptions, and alleges that it *848 was an object of the conspiracy that defendants Michael and Laing and others would deliver, distribute, and dispense controlled substances, including Butalbital, a Schedule III controlled substance, by means of the Internet, and aided and abetted each other in doing so, in a manner not authorized by the Controlled Substances Act, Chapter 841 of Title 21 U.S.C. SSI, ¶¶ 24-29.

As noted herein, the indictment must be read as a whole. The SSI adequately charges a conspiracy to unlawfully distribute and dispense controlled substances inasmuch as Michael, Laing, and Meds 2 Go are alleged to have knowingly and willfully conspired together and with others to engage in a scheme to sell, distribute, and dispense prescription drugs over the Internet without issuance of a valid prescription.

SSI, ¶ 23., The United States summarily explains that "the. factual allegations in the Second Superseding Indictment... describe how [the defendants] schemed to defraud customers of their money, by intentionally misleading customers to believe that the prescription drugs purchased from the RX Limited websites were legally prescribed and dispensed." The allegations, when read as a whole, support this summary description.

Paragraph 23 describes the process by which purchases of prescription drugs were made from the RX Limited entities and then were dispensed and shipped by "Filling Pharmacies" such as Meds 2 Go and Aracoma Pharmacy. The SSI states that the prescription websites would provide an online medical questionnaire relating to the drug the customer wished to purchase, often prepopulating certain answers so that the customer would not be disqualified from- receiving that drug.

Often the website would represent that a "physician consultation" was required pri- or to the order being filled. However, it is alleged that the customer would complete the transaction, paying on-line with a credit card, and then receive the drug, without the physician consultation having been done.

The SSI describes that, unbeknownst to the customer, the website operator would send the completed medical questionnaire to an "Issuing Doctor"⁴ who would, without any sort of

consultation or contact with the customer or verification of the information provided, issue a prescription which was, thus, invalid.

Accordingly, there was a “loss” to the customer, despite the customer’s receipt of the drug in the mail. As explained in *United States v. Ihenacho*, 716 F.3d 266, 277 (1st Cir. 2013), “From the face, of it, the consumers had received entirely legally prescribed drugs. But in fact, they had not.” The Ihenacho court quoted from *United States v. Bhutani*, 266 F.3d 661, 670 (7th Cir.

2001) which held that “[T]here was indeed loss to consumers because consumers bought drugs under the false belief that they were in full compliance with the law.” Additionally, the Ryan Haight Online Pharmacy Consumer Protection Act amended the Controlled. Substances Act to require that certain disclosures be made on internet pharmacy websites.

The statute requires the posting in a visible and clear manner on the homepage of each online pharmacy or site to which such pharmacy is hyperlinked that “This online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. ■ This in-
*849eludes at least one prior in-person medical evaluation or medical evaluation via tele-medicine, in accordance with applicable requirements of section 309.” 21 U.S.C; § 831(c)(7); Such disclosure informs a prospective customer, among other things, what interaction between doctor and patient is required for the doctor to write a valid prescription for that patient.

The disclosure also requires that the website notice unequivocally state that “this online pharmacy will only dispense a controlled substance to a person who has a valid prescription.” The SSI alleges that the filling pharmacy completing the orders in this case omitted this statutorily-required information. SSI, ¶ 23(k). This notice would arguably have provided potential customers with information material to their decision to do business with the online pharmacy.

The defendants contend that under the facts alleged in the SSI, a pharmacist could unknowingly fill invalid prescriptions issued by a licensed physician. This argument- is nothing more than the defense that the defendants were not conspirators. What is required of the indictment, however, is merely a recitation of facts sufficient to inform the defendants of the crime with which they are charged.

The United States has alleged the time period, the means, and the objects of the alleged agreement between the defendants.'The SSI charges the defendants with knowingly and intentionally conspiring to engage in this scheme, and informs the defendants of the acts which he allegedly engaged in during the existence of the conspiracy.

The United States must, of course, prove that the defendants knowingly and intentionally joined in the agreement to engage in unlawful activity. However, the United States need not prove its case in response to a motion to dismiss. - To obtain a conviction under section 846, the government must

prove the existence of an agreement to violate the drug laws and that each conspirator knew of, intended to join and participated in the conspiracy.

United States v. Pearce, 912 F.2d 159, 161 (6th Cir. 1990)(citation omitted). As noted in United States v. Blakeney, 942 F.2d 1001, 1010 (6th Cir. 1991), The government need not prove that the agreement was formal or express. United States v. Ellzey, 874 F.2d 324, 328 (6th Cir. 1989). “A conspiracy may be inferred from circumstantial evidence that can reasonably be interpreted as participation in the common plan.” United States v. Bavers, 787 F.2d 1022, 1026 (6th Cir.

1985). The existence of a conspiracy to violate federal law may be established by a tacit or mutual understanding, among the parties. United States v. Hughes, 891 F.2d 597, 601 (6th Cir. 1989). We note, however, that “‘mere association with conspirators is not enough to establish participation in a conspiracy.’” Pearce, 912 F.2d at 162 (citation omitted). 942 F.2d at 1009-10.

Our focus here must not be on the defendants’ assertion of “mere association” and thus unknowing participation in the scheme, but rather whether the SSI alleges facts sufficient to inform the defendants of the specific conspiracy which they are charged with knowingly and intentionally joining.

We find that the SSI sufficiently so informs these defendants. The SSI alleges that it was an object of the conspiracy that Michael and Laing would, and that they did, deliver, distribute, and dispense controlled substances by means of the Internet in a manner not authorized by Subchapter I of Chapter 13 of Title 21, United States Code, and thus violated 21 U.S.C. § 841(h)(1)(A)-(B).

21 U.S.C. ■§ 841(h)(1)(A)-(B) states that “It *850shall 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; or (B) aid or abet... any activity described in subparagraph (A) that is not authorized by this subchapter.” The Controlled Substances Act (“CSA”) includes 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 •...,” unless specifically exempted.

21 U.S.C. § 812(c), Schedule III (b)(1). Count 1 alleges that Fiorieet, a prescription drug containing Butalbital, was a Schedule III controlled substance. The United States contends that Butalbital is a derivative of barbituric acid.

The SSI alleges: 18. Fiorieet was a prescription drug, containing butalbital, acetaminophen, and caffeine, and was approved to treat tension headaches. Butalbital, a barbiturate, was a Schedule III controlled substance under the CSA, and was habit-forming and potentially abusable. 21 C.F.R. § 1308.13... 30.

The controlled substance involved in the above listed offense was Butalbital, a Schedule III controlled substance, among other Prescription Drugs. SSI, ¶¶ 18, 30. The defendants contend that Fioricet, the prescription drug identified in Count 1, “falls within the ‘unless specifically exempted’ language of 21 U.S.C. 812(c), Schedule 111(b)(1),” and therefore was not a “controlled substance” during the time period described in the SSI.

Alternatively, the defendants urge that even if Fioricet was a controlled substance, it was not illegal to dispense it without a valid prescription, as Fioricet was exempted from the prescription and registration requirements by virtue of regulation 21 C.F.R. 1308.32. DN 50-1, pp. 7-9. Other courts have consistently rejected the argument that Fioricet is not a controlled substance.

In the case of *United States v. Oz*, Crim. No. 13-00273, 2017 WL 342069 (D. Minn. Jan. 23, 2017) (“*Oz II*”),⁵ for example, a case involving charges similar to those brought here, the United States District Court for the District of Minnesota found: Defendants are charged with a variety of offenses related to their involvement with an online pharmacy, RX Limited (“RXL”)...

In relevant part, Defendants Moran Oz, Babubhai Patel, La-chlan McConnell, and Elias Karkalas, are charged with violating the Controlled Substances Act (“CSA”) by: (1) dispensing a drug known as Fioricet without valid prescriptions as required by 21 U.S.C. § 829(e); (2) dispensing Fioricet through RXL and its affiliates, which were not registered with the Drug Enforcement Agency (“DEA”) as required by 21 U.S.C. § 823(f); and, (3) dispensing Fioricet through RXL, which did not display certain information on its website(s) as required by 21 U.S.C. § 831...

The Government charges that Defendants’ failures to abide by the requirements of 21 U.S.C. §§ 823(f), 829(e), and 831 constituted criminal violations of 21 U.S.C. § 841(h)(1)... Fioricet is a combination drug consisting of acetaminophen, caffeine, and butalbital (which is a derivative of barbituric acid) and is used to treat tension headaches. (See Indict, at 7.)

Butalbital is a Schedule III controlled substance. 21 *851 U.S.C. § 812, Sch. 111(b)(1). Thus, Fioricet is a controlled substance because it contains butalbital. *Id.*; *Oz*, 2016 WL 1183041 at *3-5; *United States v. Akinyoyenu*, No. CR 15-42 (JEB), 199 F.Supp.3d 106

12, J.

, 2016 WL 4151040, at *3-4 (D.D.C. Aug. 4, 2016); *United States v. Riccio*, 43 F.Supp.3d 301, 304-05 (S.D.N.Y. 2014); *United States v. Williams*, No. CR-10-0216-HE, 2010 WL 4669180, at *1 (W.D. Okla. Nov. 9, 2010), *aff’d*, 549 Fed.Appx. 813 (10th Cir. 2013).

The court went on to note that “this does not end the inquiry since Defendants’ argument rests on an exemption related to certain provisions of the CSA.” *Id.* As explained in *Oz II*, The DEA,⁶ through a proper delegation of authority by the Attorney General, is empowered to “exempt any

compound, mixture, or preparation containing a controlled substance from the application of all or any part” of Subchapter I of the Controlled Substances Act.

21 U.S.C. § 811(g)(3). By virtue of this authority, the DEA enacted a regulation stating that certain “compounds, mixtures, or preparations that contain a nonnarcotic controlled substance [including Fioricet]... have been exempted... from [various statutes and regulations] for administrative purposes only.” 21 C.F.R. § 1308.32 (emphasis added)...

In *Akinyoyenu*, supra,⁷ the defendant was charged with violating 21 U.S.C. § 841 for dispensing Fioricet through an online pharmacy without a valid prescription. *Id.* at 109. In moving to dismiss the charges under the CSA, he argued that Fioricet was not a controlled substance. *Id.* at 110.

The court rejected this argument and concluded that the Exempting Regulation, by its plain language, did not exempt Fioricet from application of the statute establishing its general classification as a Schedule III controlled substance. *Id.* at 112. This court agrees. Fioricet remains a schedule III controlled substance despite the DEA’s exemption of certain substances from application of select sections of the CSA.

The DEA, empowered to “exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part of Subchapter I of the Controlled Substances Act,” exempted Fioricet “from the application of sections 302 through 305, 307 through 309, and 1002 through 1004 of the Act... and §§ 1301.13, 1301.22, and §§ 1301.71 through 1301.76 of this chapter for administrative purposes only.” 21 C.F.R. § 1308.32 (referred to as the “Exempting Regulation”).

Among these sections is § 829 which states that except when dispensed directly by a practitioner, other than a pharmacist, to a patient, no controlled substance which is a prescription drug under the Federal Food, Drug, and Cosmetic Act, may be dispensed without a valid prescription.

The defendants contend that the DEA’s exemption from the application of this section constitutes an authorization to distribute Fioricet without a prescription. The defendants cite to *Akinyoyenu* in support of this position.

In *Akinyoyenu*, the court held that the defendants could not be subjected to criminal prosecution for distribution of Fioricet without a prescription. Judge Boasberg⁸ concluded that it “made little sense” to read the exemption to immunize physicians and pharmacists from administrative, but not criminal- enforcement. *Id.* at 115. *Id.* He found that such an interpretation of 21 C.F.R. 1308.32 would be a “mindless endeavor,” rendering 1308.32 “meaningless” and “gratuitous.” *Id.* at 116.

Having received no argument from the United States concerning the purpose of affording an administrative, but not criminal, exemption, Judge Boasberg concluded that although preserved from prior iterations of the regulation the language ““for administrative purposes only”¹ might now

very well mean nothing at all.” Id. at 117. With no assistance from the United States, he followed a “trail of breadcrumbs” offered by Akiyoyenu which arrived at the conclusion that the phrase was a “now-obsolete holdover from an era when the regulation’s original 1971 language gave only an interim list of exempted drugs.” Id. at 116.

The defendant theorized that “for administrative purposes only” was meant to signal “lack of finality,” and that fifty years later with the drug criteria finalized, the DEA simply forgot about the phrase, and that it should be held for naught in the court’s present analysis of the effect of the exemption. Accepting this theory as “unimpeached by the Government,” Id., Judge Boasberg chose not to give effect to the phrase “for administrative purposes only,” and concluded that the exemption from the prescription requirement found in § 829 authorized the dispensing of Fioricet without a valid prescription.

Id. at 114, 118. This court, too, lacks a substantive argument from the United States beyond the assertion that Oz II, juxtaposed to Alci-nyoyenu, was the correctly decided case. We do not believe, however, that the court should divine⁹ the meaning of a phrase which ■ is clear and unambiguous.

As explained in Oz II, [T]here is no need to interpret the history behind the “for administrative purposes only” phrase — the plain language is clear and unambiguous. See *Lamie v. U.S. Tr.*, 540 U.S. 526, 534 [124 S.Ct. 1023, 157 L.Ed.2d 1024] (2004) (“The starting point in discerning congressional intent is the existing statutory text and not the predecessor statutes.

It is well established that when the statute’s language is plain, the sole function of the courts — at least where the’ disposition required by the text is not absurd — is to enforce it according to its terms.” (citations and quotations omitted)); *Contemporary Indus. Corp. v. Frost*, 564 F.3d 981, 985 (8th Cir. 2009) (“[I]f the relevant text is not reasonably susceptible to more than one interpretation, we will not look beyond it unless application of the plain language will produce a result demonstrably at odds with the’ intentions of its drafters.” (quotations omitted)) [[Image here]] 2017 WL 342069 at *4.

Judge Boasberg noted that “[t]hough 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.” Id. at 117. There is no question that the administrative and criminal provisions, set forth in statutes and implemented through regulations, complement each other.

Rather, the question is whether we should find them hopelessly in lockstep. We do not. *853 Judge Boasberg found that “[t]he Government itself would seemingly lose much by discarding administrative enforcement while hanging on only to criminal enforcement.” Id. at 118. He notes that “nothing in the CSA expressly tells individuals that they can distribute Fioricet without a prescription.” Id. at 115.

Yet he expresses concern over the lack of benefit to the regulatee, such as a pharmacist, who would purportedly find no safe harbor if criminal prosecution was still possible. We know of no authority that requires a regulation to benefit the regulatee. Additionally, although perhaps of little practical benefit to a pharmacist who remains cognizant of the possibility of criminal prosecution, exemption from certain oversight in the administrative sphere may be welcome.

This court is of the view that the rationale of Judge Nelson¹⁰ in *Oz II* to be the better reasoned approach. We agree with Judge Nelson that there is no need to interpret the history behind the plain language of the unambiguous phrase “for administrative purposes only.” Thus, while Judge Boasberg’s erudite analysis of the regulatory history is interesting, we find it unconvincing in light of the regulation’s clarity.

Further, even if the phrase “for administrative purposes only” was a remnant, as he suggests, we do not find it proper to simply ignore it. As noted by Judge Nelson, the regulation has been altered a number of times, yet the phrase remains.

We find this indicative of deliberate action in leaving the phrase in, rather than neglect in failing to take it out. Judge Boasberg goes to great lengths to jettison from the phrase which embodies it, by purporting to look at what the phrase does to the effectiveness of the exemption, concluding that it renders the Exempting Regulation “practically ineffective.” *Akinyoyenu*, 199 F.Supp.3d at 117.

Respectfully, we find that it does no such thing. ■ -, - ' We think it important to look at the sentence structure of § 1308.32. It states, in sum, that “compounds, [etc.]... have, been exempted..’ from the application of [various statutory and regulatory provisions]... for administrative- purposes only.” The exemption is thus limited to “administrative purposes.”- Whatever “administrative purposes” may be, we know to a level certainty, what it is not.

It is criminal proceedings. While complementary, as suggested by Judge Boasberg, administrative and criminal enforcement are independent- of one another. We therefore reject the notion that “for administrative purposes only” somehow emasculates the regulation and thus must be excised to save its functional benefit. This would be throwing the baby out with the bathwater for no legitimate reason.

Judge Boasberg offers sharp criticism, urging that it is nonsensical to relieve individuals from administrative penalties, yet leave them exposed' to criminal prosecution with its attendant' more serious punishments.

However, the imposition of criminal penalties requires that there first be a criminal conviction under the-standard of proof of beyond a reasonable doubt. Judge Boasberg urges that “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.” *Id.* at 116.

Just so. Fioricet is a controlled substance. The Exempting Regulation did not change that. Fioricet is a prescription drug under the FDCA. Fioricet may not be dispensed, in this case, by a pharmacist, without a valid prescription.

The statute so ⁸⁵⁴stating, § 829 remains the law. A pharmacist who fails to meet the requirements of the law should be wary of criminal prosecution for such conduct. The fact that one is exempt from the application of the section for administrative purposes only is, in fact, beside the point.

Although not specifically argued here, we note that Judge Nelson found that [The Exempting Regulation] represents a reasonable agency decision to preserve resources and forgo administrative enforcement while preserving the ability to address “serious criminal misconduct—such as cases where doctors authorize hundreds of drug orders a day based solely on customer-provided questionnaires over the Internet....

This is especially true since administrative and criminal enforcement under the CSA are distinct.” See *Riccio*, 43 F.Supp.3d at 305-06 (“[T]he statutory and regulatory framework make clear that administrative enforcement for violations of the Controlled Substantive Act is entirely separate and distinct from criminal prosecutions like this one.” (citing 21 C.F.R. § 1301.41(b) and 21 U.S.C. § 847)); *Oz*, 2016 WL 1183041 at *4 (same)...

[U]nderstanding the Exempting Regulation to “authorize” the distribution of Fioricet without a valid prescription would lead to an illogical result. Dispensing Fioricet without a valid prescription is criminal under the Food, Drug, and Cosmetic Act (“FDCA”). See 21 U.S.C. §§ 331(a), 333(a), 353(b); *United States v. Smith*, 573 F.3d 639, 650-53 (8th Cir. 2009) (holding that the prescription required by the FDCA must come in the usual course of professional practice, be for a legitimate medical purpose, and be the result of a bona fide physician-patient relationship).

The Court agrees with the Government that adopting Defendants’ view of the Exempting Regulation would create “an odd regulatory regime whereby issuing Fioricet without a valid prescription is unlawful under one law regulating prescription drugs [the FDCA] and permissible under a second law regulating prescription drugs that also contain a controlled substance [the CSA].” (Gov’t’s Resp. at 10-11)...

Id. at 4-5. Finally, we disagree that the rule of lenity should be applied in this instance. The defendants urge that “[i]f two district courts cannot agree whether Fioricet is exempt from the prescription requirement of the CSA, a pharmacist, without legal training, should not be held criminally liable for allegedly knowingly violating a law that is not settled.” DN 130, p. 5.

We agree with Judge Nelson that “the Exempting Regulation is difficult to understand only if one assumes that the “for administrative purposes only” language means something other than what it says or is without meaning.” *Oz II*, at *5, n. 5.

The CSA makes it unlawful, except as authorized, to dispense a controlled substance by means of the Internet. Thus, a plain reading of the Exempting Regulation does not suggest that it authorizes conduct which is otherwise proscribed by the CSA.

We find no ground to refer to the rule of lenity in this analysis. Upon this reasoning, we conclude, as did the court in *Oz II*, that “The Exempting Regulation does not authorize the distribution of Fioricet without a valid prescription or through an online pharmacy that lacks DEA registration for the purposes of criminal charges under 21 U.S.C. § 841(h)(1).” *Id.* at 5.

The motion of the defendants to dismiss Count 1 ' of the SSI (DN 50) will be DENIED. A separate order will be entered *855herein this date in accordance with this opinion. IT IS SO ORDERED.. Defendant Euton Laing is named in these counts but has not moved for dismissal..

The United States has indicated that it intends to proceed under the Second Superseding Indictment. This court will therefore address whether the charges therein are able to withstand the challenges raised in the present motion..The invalidity of the prescriptions is detailed in ¶ 23.. According to-the SSI, an “Issuing Doctor” was an individual who may or may not have been a licensed physician..

The *Oz* court incorporated its prior opinion. *United States v. Oz*, Criminal No. 13-00273 (SRN/JJK), 2016 WL 1183041 (D. Minn. Mar. 28, 2016)(“*Oz I*”) into its 2017 opinion., *The United States Drug Enforcement Administration*.. Now published as *United States v. Akinyoyenu*, 199 F.Supp.3d 106 (D.D.C. 2016)..

The Honorable James E. Boasberg, USDC, D.D.C.. Divination was Judge Boasberg’s word, not ours. He acknowledged in his opinion that “interpreting those few words [“for administrative purposes only”] demands some powerful divination.” *Id.* at 116.

We need not read the tea leaves of regulatory history where the plain language of the regulation is clear.. The Honorable Susan Richard Nelson, USDC, P.Minn.